

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

DARRELL GOTHARD, JEFFREY	:	
GROUDAN, GAIL GILLIARD-	:	
GUNTER, DON LUENEBRINK,	:	
ROBERT WAYBRIGHT, KENNETH	:	Case No. 2:22-cv-906
DZIERZANOWSKI, TARA FIELDS,	:	
BARBARA SMITH, ROY FULTZ,	:	CLASS ACTION COMPLAINT
ASHERDEE DIAMOND, DANNY	:	
BARAN, DEBBIE ROOTBERG, DIANE	:	DEMAND FOR JURY TRIAL
ANDERSON, JOHN RATLIFF, LULA	:	
MINNIFIELD, JULIE BARRETT,	:	
PETER BARRETT, DORIS	:	
MARGOLES, RYAN SCHWARTZ,	:	
HEIDI MCGUIRE, WILLIAM WILKS,	:	
GRADY TUCKER JR., JOHN YOUNG,	:	
DANNY DAVID, SUSANNE DENNIS,	:	
AARON TAYLOR, SONIA DIAZ,	:	
SUSAN WOODWARD, PATRICIA	:	
FLICK, JACK GIORDANO, RACHEL	:	
HOCK, VINCENT STEFANINI, JASON	:	
MCELYEA, JOHN MASINGTON,	:	
WILLIAM ANDERSON, RAUL	:	
DELEON, SARAH LOWNEY, PAUL	:	
PANZERA, ROSITA POLK, and	:	
ROBERT MATTERS, on behalf of	:	
themselves and all others similarly	:	
situated,	:	

Plaintiffs,

v.

KONINKLIJKE PHILIPS N.V., PHILIPS	:	
NORTH AMERICA LLC, PHILIPS	:	
HOLDING USA INC., PHILIPS RS	:	
NORTH AMERICA LLC, and PHILIPS	:	
RS NORTH AMERICA HOLDING	:	
CORPORATION,	:	

Defendants.

Plaintiffs Darrell Gothard, Jeffrey Groudan, Gail Gilliard-Gunter, Don Luenebrink, Robert Waybright, Kenneth Dzierzanowski, Tara Fields, Barbara Smith, Roy Fultz, Asherde Diamond, Danny Baran, Debbie Rootberg, Diane Anderson, John Ratliff, Lula Minnifield, Julie Barrett, Peter Barrett, Doris Margoles, Ryan Schwartz, Heidi McGuire, William Wilks, Grady Tucker Jr., John Young, Danny David, Susanne Dennis, Aaron Taylor, Sonia Diaz, Susan Woodward, Patricia Flick, Jack Giordano, Rachel Hock, Vincent Stefanini, Jason Mcelyea, John Masington, William Anderson, Raul Deleon, Sarah Lowney, Paul Panzera, Rosita Polk, and Robert Matters, individually and on behalf of all others similarly situated, through the undersigned counsel, allege as follows.

I. NATURE OF THE ACTION

1. Defendants Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA Inc., Philips RS North America LLC, and Philips RS North America Holding Corporation, collectively, (“Philips”) manufacture and sell certain lines of products that are intended to help people breathe. These include Continuous Positive Airway Pressure (“CPAP”) and Bilevel Positive Airway Pressure (“BiPAP”) machines, which are commonly used to treat sleep apnea, and mechanical ventilators (“ventilators”), which treat respiratory failure. In general, these devices blow air into patients’ airways. CPAP and BiPAP machines are intended for daily use, and ventilators are used continuously when needed.

2. On June 14, 2021, Philips announced a recall of millions of its CPAP and BiPAP machines and ventilators (the “Recall”). Each of these recalled products (referred to herein as a “Recalled Device” or collectively as the “Recalled Devices”) contained polyester-based polyurethane (“PE-PUR”) foam used by Philips for sound abatement. The PE-PUR foam was provided by, among others, Polymer Technologies, Inc. (“PolyTech”). Despite knowing at least as

far back as 2015 that PE-PUR foam would degrade and that this foam should not be used in the Recalled Devices, Philips waited until June 2021 to issue the Recall and notify the public. In its Recall, Philips publicly announced that the PE-PUR foam may break down into particles and be inhaled or ingested, or may emit volatile organic compounds (“VOCs”) that may be inhaled, resulting in “serious injury, which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment”¹ (referred to herein as the “Defect”). Philips stated that the potential risks of exposure due to such chemicals include “headache/dizziness, irritation (eyes, nose respiratory tract, skin), hypersensitivity, nausea, vomiting, toxic and carcinogenic effects.”² Philips’ announcement to doctors advised that these hazards could result in “serious injury which can be life-threatening or cause permanent impairment.”³

3. On July 22, 2021, the U.S. Food and Drug Administration (“FDA”) confirmed the severity of the problem and classified the Recall as Class I or “the most serious type of recall,” meaning use of the Recalled Devices “may cause serious injuries or death.”⁴

4. Philips knew about the serious risks caused by the Recalled Devices long before the Recall. According to the FDA, beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the Recalled Devices, including complaints, test reports, information from suppliers, and information from another entity owned by the ultimate parent company of Philips.

¹ Philips Recall Notices dated 6/14/2021 (attached hereto as Exhibit “A”). All attached Exhibits and reference material are incorporated as if fully stated herein.

² *Id.*

³ *Id.*

⁴ <https://www.fda.gov/medical-devices/medical-device-recalls/philips-respirronics-recalls-certain-continuous-and-non-continuous-ventilators-including-cpap-and> (last accessed June 16, 2022).

5. Philips notified its shareholders about the Defect in the Recalled Devices in late April 2021, but even then, did not initiate the Recall of the dangerously defective machines until June 14, 2021.

6. In fact, Philips apparently timed its Recall to coincide with its launch of a next generation of the affected products, which Philips claims does not suffer from the same defective and harmful foam issues. Thus, at the time of the Recall, the only purportedly safe option that Philips offered to its customers—many of whom require a BiPAP or CPAP machine to sleep safely—was to purchase, *at full price*, Philips’ new, next-generation device, profiting Philips further.

7. Because of the increased demand for safe and effective CPAP, BiPAP, and ventilator devices, replacement machines are difficult to find and expensive, a situation that was exacerbated by a shortage of microchips for these devices. Thus, many users were forced into a Hobson’s choice—continue using their Philips’ Recalled Devices and expose themselves to risks of serious injury or death or stop using their breathing devices and risk health consequences from their underlying conditions.

8. Philips’ flagship line and top seller of its CPAP Recalled Devices are its DreamStation devices. On September 1, 2021, Philips received authorization from the FDA to begin a repair and/or replacement process for affected DreamStation devices in the United States.⁵ DreamStation customers, however, were not told when they might receive a replacement device, nor were they given any specifics as to how the replacement program would work. Moreover, the

⁵ <https://www.usa.philips.com/healthcare/resource-catalog/landing/experience-catalog/sleep/communications/src-update/news/phillips-starts-repair-and-replacement-program-of-first-generation-dreamstation-devices-in-the-us-and-other-markets> (last accessed June 16, 2022).

repair and/or replacement process was only for DreamStation Recalled Devices and did not encompass any other Recalled Device.

9. The Recalled Devices are:

- E30
- DreamStation ASV
- DreamStation ST, AVAPS
- SystemOne ASV4
- C Series ASV, S/T, AVAPs
- OmniLab Advanced Plus
- SystemOne (Q Series)
- DreamStation CPAP, Auto CPAP, BiPAP
- DreamStation Go CPAP, APAP
- Dorma 400, 500 CPAP
- REMStar SE Auto CPAP
- Trilogy 100 and 200
- Garbin Plus, Aeris, LifeVent
- A-Series BiPAP Hybrid A30
- A-Series BiPAP V30 Auto
- A-Series BiPAP A40
- A-Series BiPAP A30

10. All of the Recalled Devices suffer from the same problem, the use of the PE-PUR foam.

11. Each of the Plaintiffs acquired or paid for a Recalled Device. They would not have purchased or leased the Recalled Device had they known that the PE-PUR foam in the Recalled Device could expose users to life-threatening injuries or cause serious health problems, rendering the Recalled Device defective and unsafe, and not fit for their intended purpose.

12. Plaintiffs, individually and on behalf of all others similarly situated who purchased or leased the defective Recalled Devices, seek to recover compensatory and punitive damages from Philips for breach of express warranty, breach of the implied warranty of merchantability, breach of the implied warranty of usability, failure to warn, design defect, fraud, unjust enrichment, rehhibition, and applicable state consumer protection statutes.

II. THE PARTIES

A. PLAINTIFFS

13. Plaintiff Darrell Gothard (“Gothard”) is and at all relevant times was a citizen of Alabama and the United States. Plaintiff acquired a Philips Resironics DreamStation on or about 2015, in Alabama. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

14. Plaintiff Jeffrey Groudan (“Groudan”) is and at all relevant times was a citizen of Arizona and the United States. Plaintiff acquired a Philips DreamStation on or about November 2020, in Arizona. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

15. Plaintiff Gail Gilliard-Gunter (“Gilliard-Gunter”) is and at all relevant times was a citizen of the United States and has lived in Arizona and Louisiana since acquiring a recalled device. Plaintiff acquired a Philips DreamStation on or about 2017 while residing in Louisiana and a Philips DreamStation BiPAP on or about January 2020 while residing in Arizona. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

16. Plaintiff Don Luenebrink (“Luenebrink”) is and at all relevant times was a citizen of California and the United States. Plaintiff acquired a Philips DreamStation on or about September 2019, in California. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

17. Plaintiff Robert Waybright (“Waybright”) is and at all relevant times was a citizen of California and the United States. Plaintiff acquired a Philips DreamStation on or about March 2016, in California. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

18. Plaintiff Kenneth Dzierzanowski (“Dzierzanowski”) is and at all relevant times was a citizen of Florida and the United States. Plaintiff acquired a Philips DreamStation on or about the Summer of 2019, in Florida. Plaintiff was unaware of the Defect at the time of acquisition, and

Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

19. Plaintiff Tara Fields ("Fields") is and at all relevant times was a citizen of Florida and the United States. Plaintiff acquired a Philips DreamStation in or around September 2020, in Florida. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

20. Plaintiff Barbara Smith ("Smith") is and at all relevant times was a citizen of Florida and the United States. Plaintiff acquired a Philips DreamStation in the spring of 2017, and a second DreamStation in April 2018, in Florida. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have acquired the devices. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Devices and costs associated with the Recall.

21. Plaintiff Roy Fultz ("Fultz") is and at all relevant times was a citizen of the United States and has lived in Ohio and Georgia since acquiring the Recalled device. Plaintiff acquired a Philips SystemOne on or about 2016, in Georgia. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have acquired the device. Plaintiff seeks full

reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

22. Plaintiff Asherdee Diamond (“Diamond”) is and at all relevant times was a citizen of Idaho and the United States. Plaintiff acquired a Philips REMStar on or about 2016, and a Philips DreamStation on or about 2019, in Idaho. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff’s devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s devices, Plaintiff would not have acquired the devices. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Devices and costs associated with the Recall.

23. Plaintiff Danny Baran (“Baran”) is and at all relevant times was a citizen of Illinois and the United States. Plaintiff acquired a Philips DreamStation in or about February 2019 in Illinois. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

24. Plaintiff Debbie Rootberg (“Rootberg”) is and at all relevant times was a citizen of Illinois and the United States. Plaintiff acquired a Philips System One on or about June 2012, in Illinois. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

25. Plaintiff Diane Anderson is and at all relevant times was a citizen of Indiana and the United States. Plaintiff acquired a Philips DreamStation on or about December 2019, in Indiana. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

26. Plaintiff John Ratliff ("Ratliff") is and at all relevant times was a citizen of Kentucky and the United States. Plaintiff acquired a Philips DreamStation on or about 2018, in Kentucky. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

27. Plaintiff Lula Minnifield ("Minnifield") is and at all relevant times was a citizen of Louisiana and the United States. Plaintiff acquired a Philips DreamStation on or about January 2019, in Louisiana. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the recalled device and costs associated with the Recall.

28. Plaintiff Julie Barrett is and at all relevant times was a citizen of the United States and has lived in Maine and Oregon since acquiring a Recalled Device. While residing in Maine, Plaintiff acquired a Philips DreamStation on or about July 2018 from a provider in New

Hampshire. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

29. Plaintiff Peter Barrett is and at all relevant times was a citizen of the United States and has lived in Maine and Oregon since acquiring a Recalled Device. While residing in Maine, Plaintiff acquired a Philips DreamStation on or about July 2018 from a provider in New Hampshire. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

30. Plaintiff Doris Margoles ("Morgales") is and at all relevant times was a citizen of the United States and has resided in Maine and North Carolina since acquiring the Recalled Device. Plaintiff acquired a Philips DreamStation CPAP on or about 2017, in Maine. Plaintiff now lives in North Carolina. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

31. Plaintiff Ryan Schwartz ("Schwartz") is and at all relevant times was a citizen of Maine and the United States. Plaintiff acquired a Philips DreamStation on or about January 19,

2018, in Maine. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

32. Plaintiff Heidi McGuire ("McGuire") is and at all relevant times was a citizen of Michigan and the United States. Plaintiff acquired a Philips DreamStation on or about January 2018, in Michigan. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

33. Plaintiff William Wilks ("Wilks") is and at all relevant times was a citizen of Michigan and the United States. Plaintiff acquired a Philips DreamStation on or about December 2020, in Michigan. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

34. Plaintiff Grady Tucker, Jr. ("Tucker") is and at all relevant times was a citizen of Mississippi and the United States. Plaintiff acquired a Philips DreamStation on or about August 29, 2016, and a Philips DreamStation Go on or about June 2, 2021, in Mississippi. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have

acquired the devices. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Devices and costs associated with the Recall.

35. Plaintiff John Young (“Young”) is and at all relevant times was a citizen of Missouri and the United States. Plaintiff acquired a Philips DreamStation CPAP on or about January 2021, in Missouri. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

36. Plaintiff Danny David (“David”) is and at all relevant times was a citizen of Montana and the United States. Plaintiff acquired a Philips DreamStation Auto CPAP on or about January 2021, in Montana. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

37. Plaintiff Susanne Dennis (“Dennis”) is and at all relevant times was a citizen of New Jersey and the United States. Plaintiff acquired a Philips DreamStation Auto CPAP on or about November 2018, in New Jersey. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full

reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

38. Plaintiff Aaron Taylor (“Taylor”) is and at all relevant times was a citizen of New Jersey and the United States. Plaintiff acquired a Philips DreamStation in or around late 2015/early 2016, in New Jersey. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

39. Plaintiff Sonia Diaz (“Diaz”) is and at all relevant times was a citizen of the United States and since acquiring the Recalled Device has lived in New York and South Carolina. Plaintiff acquired a Philips DreamStation Auto CPAP in October 2016, in New York. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

40. Plaintiff Susan Woodward (“Woodward”) is and at all relevant times was a citizen of New York and the United States. Plaintiff acquired a Philips DreamStation on or about December 2018, in New York. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a

replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

41. Plaintiff Patricia Flick (“Flick”) is and at all relevant times was a citizen of Ohio and the United States. Plaintiff acquired a Philips REMstar CPAP machine on or about October 2012, in Ohio. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

42. Plaintiff Jack Giordano (“Giordano”) is and at all relevant times was a citizen of Ohio and the United States. Plaintiff acquired a Philips DreamStation on or about January 2016, in Ohio. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

43. Plaintiff Rachel Hock (“Hock”) is and at all relevant times was a citizen of Ohio and the United States. Plaintiff acquired a Philips System One on or about 2014, and a Philips DreamStation CPAP on or about November 2018, in Ohio. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff’s devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s devices, Plaintiff would not have acquired the devices. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Devices and costs associated with the Recall.

44. Plaintiff Vincent Stefanini (“Stefanini”) is and at all relevant times was a citizen of Ohio and the United States. Plaintiff acquired a Philips DreamStation on or about November 2019, in Ohio. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

45. Plaintiff Jason Mcelyea (“Mcelyea”) is and at all relevant times was a citizen of Oklahoma and the United States. Plaintiff acquired two Philips DreamStations on or about 2020, in Oklahoma. Plaintiff was unaware of the Defects at the time of acquisition, and Plaintiff’s devices was included in the Recall. Had Plaintiff been aware of the Defects in Plaintiff’s devices, Plaintiff would not have acquired the devices. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Devices and costs associated with the Recall.

46. Plaintiff John Masington (“Masington”) is and at all relevant times was a citizen of Pennsylvania and the United States. Plaintiff acquired a Philips DreamStation on or about December 19, 2016, and a second Philips DreamStation on or about April 24, 2017, in Pennsylvania. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff’s devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s devices, Plaintiff would not have acquired the devices. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Devices and costs associated with the Recall.

47. Plaintiff William Anderson is and at all relevant times was a citizen of South Carolina and the United States. Plaintiff acquired a Philips DreamStation CPAP on or about June 2018, in South Carolina. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s

device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

48. Plaintiff Raul Deleon (“Deleon”) is and at all relevant times was a citizen of Texas and the United States. Plaintiff acquired a Philips DreamStation in 2016, and a DreamStation Go in 2019, in Texas. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff’s devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s devices, Plaintiff would not have acquired the devices. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Devices and costs associated with the Recall.

49. Plaintiff Sarah Lowney (“Lowney”) is and at all relevant times was a citizen of Texas and the United States. Plaintiff acquired a Philips DreamStation Auto CPAP on or about April 2021, in Texas. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

50. Plaintiff Paul Panzera (“Panzera”) is and at all relevant times was a citizen of Texas and the United States. Plaintiff acquired a Philips DreamStation on or about June 2018, in Texas. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

51. Plaintiff Rosita Polk (“Polk”) is and at all relevant times was a citizen of Texas and the United States. Plaintiff acquired a Philips DreamStation on or about October 2018, in Texas. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

52. Plaintiff Robert Matters (“Matters”) is and at all relevant times was a citizen of Wisconsin and the United States. Plaintiff acquired a Philips DreamStation in or around 2019, in Wisconsin. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have acquired the device. As a result of the Recall, Plaintiff acquired a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all costs associated with acquiring the Recalled Device and costs associated with the Recall.

B. DEFENDANTS

53. Defendant Koninklijke Philips N.V. (“Royal Philips”) is a Dutch multinational company having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of the Philips group of healthcare technology businesses including Connected Care businesses focusing on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries, Philips North America LLC and Philips RS North America LLC.⁶ As such, Royal Philips controls Philips North

⁶ Philips 2020 annual filing with the SEC, fn. 8,
<https://www.sec.gov/Archives/edgar/data/313216/000031321621000008/phg-exhibit8.htm> (last accessed June 16, 2022).

America LLC and Philips RS North America LLC with respect to the manufacturing, selling, distributing, and supplying of the Recalled Devices.⁷

54. Defendant Philips North America LLC (“Philips NA”) is a Delaware company with its principal place of business at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly-owned subsidiary of Royal Philips. Philips NA manages the operation of Royal Philips’ various lines of business, including Philips RS North America LLC, in North America. The sole member of Philips NA is Philips Holding USA Inc. Philips NA is 100% owned by Philips RS North America Holding Corporation which, in turn, is 100% owned by Philips Holding USA Inc.

55. Defendant Philips Holding USA Inc. (“PHUSA”) is a Delaware corporation with its principal place of business at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a holding company that is 100% owned, directly or indirectly, by Royal Philips. PHUSA owns 100% of Philips RS North America LLC and Philips RS North America Holding Corporation, and is the member/manager of Philips NA.

56. Defendant Philips RS North America LLC (“Philips RS”) is a Delaware company with its principal place of business at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS was formerly operated under the business name Respiromics, Inc. (“Respiromics”). Royal Philips acquired Respiromics in 2008.⁸ Philips RS is 100% owned by Philips RS North America Holding Corporation, which in turn, is 100% owned by PHUSA.

⁷ Philips 2020 annual filing with the SEC,
<https://www.sec.gov/ix?doc=/Archives/edgar/data/0000313216/000031321621000008/phg-20201231.htm> (last accessed June 16, 2022).

⁸ Philips announces completion of tender offer to acquire Respiromics, WEB WIRE,
<https://www.webwire.com/ViewPressRel.asp?aId=61199> (last accessed June 16, 2022).

57. Defendant Philips RS North America Holding Corporation (“Philips RS Holding”) is a Delaware corporation with its principal place of business at 222 Jacobs Street, Cambridge, Massachusetts 02141, and is wholly owned by PHUSA. Accordingly, Philips RS Holding is a citizen of Massachusetts and Delaware.

58. At all relevant times, each Philips Defendant acted in all aspects as the agent and alter ego of one another, and reference to “Philips” refers to each Philips Defendant individually and collectively.

III. JURISDICTION AND VENUE

59. The Court has jurisdiction under 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds \$5 million, exclusive of interest and costs, and is a class action in which Plaintiffs and some members of the Class are citizens of states different than Defendants. *See* 28 U.S.C. § 1332(d)(2)(A).

60. Venue is proper in this District under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this District.

IV. FACTUAL ALLEGATIONS

A. CPAP AND BIPAP MACHINES AND VENTILATORS ARE PRESCRIBED TO TREAT BREATHING DISORDERS.

61. Sleep apnea is a sleeping disorder in which breathing is disturbed during sleep. These disturbances are called “apneas.”

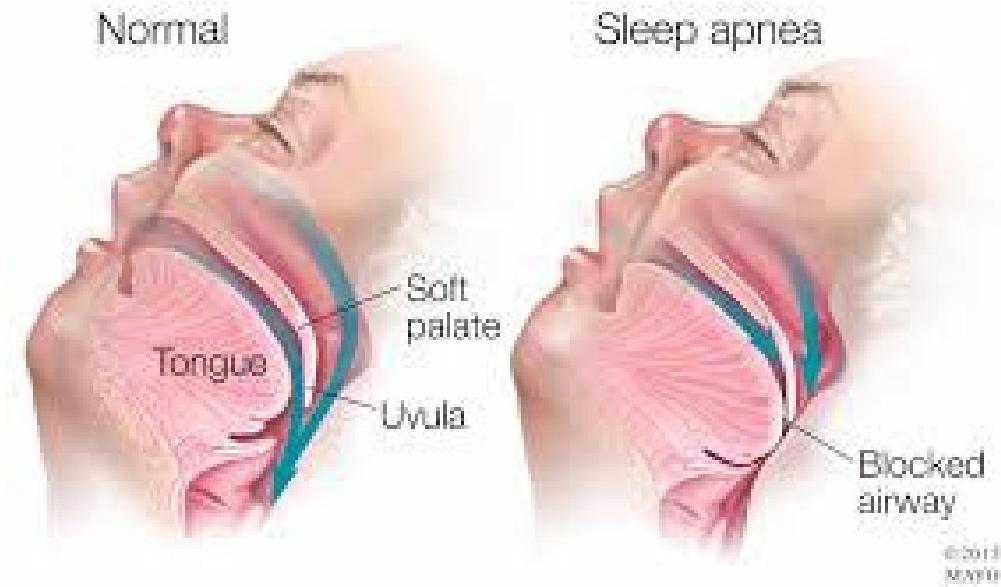
62. According to the Mayo Clinic, the main types of sleep apnea are obstructive sleep apnea, central sleep apnea, and complex sleep apnea syndrome (also known as treatment-emergent central sleep apnea).

63. Obstructive sleep apnea is the most common type. It occurs when the muscles in the back of the throat relax during inhalation, which causes the airway to narrow or close and

prevent sufficient air from passing through. This in turn lowers the oxygen level in the blood, which causes the brain briefly to wake the body from sleep to reopen the airway. This reawakening may be so brief that the patient does not remember it, and it may be associated with snorting, choking, or gasping. It can happen anywhere from a few times per hour to once every few minutes, and can prevent the patient from reaching the deep, restful phases of sleep.

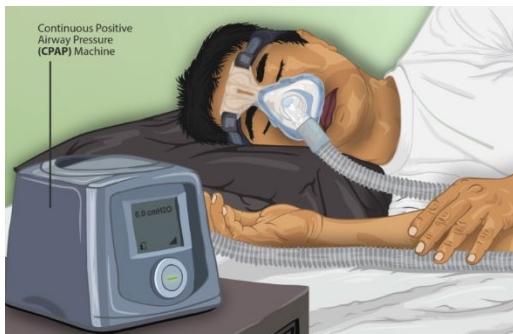
64. Central sleep apnea occurs when the brain fails to transmit signals to the breathing muscles. As a result, the body stops breathing, which can cause waking with shortness of breath or difficulty getting to sleep or staying asleep.

65. Complex sleep apnea syndrome occurs when a patient has both obstructive sleep apnea and central sleep apnea. An image showing how an airway can be blocked as a result of sleep apnea appears below:



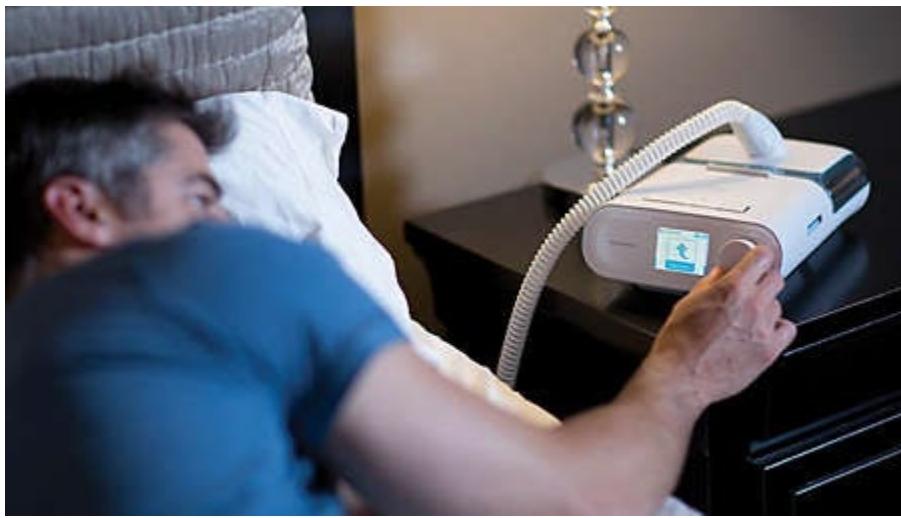
66. CPAP therapy is a common treatment for sleep apnea. In CPAP therapy, a machine delivers a flow of air through a mask over the nose or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during

sleep and can successfully treat sleep apnea. The illustration below shows a generic CPAP machine being used by a patient while sleeping.



67. Another therapy to treat sleep apnea includes use of BiPAP machines, which use two different pressures – one for inhaling and one for exhaling.

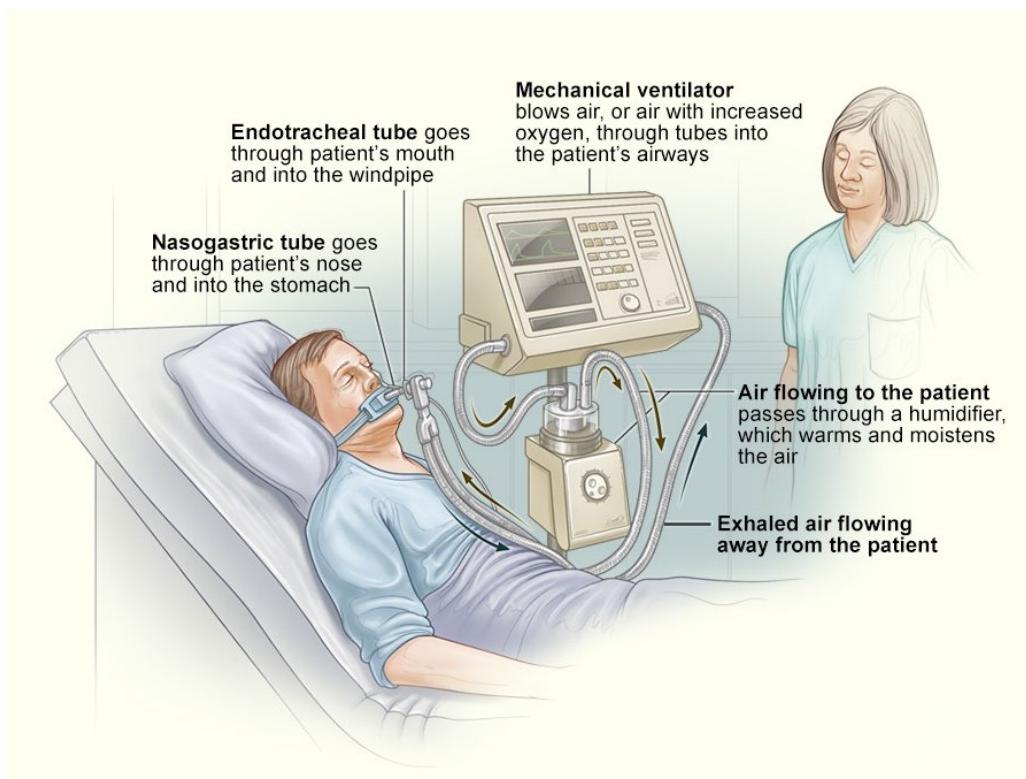
68. Patients customarily place the CPAP or BiPAP machines on a nearby nightstand or shelf. A hose connects the unit to the mask, which is worn over the nose or mouth during sleep. Below is an image of a Philips DreamStation machine on a nightstand.



69. Patients who use CPAP or BiPAP machines typically must use them every time they sleep.

70. Mechanical ventilators, usually called “ventilators,” are often used to treat respiratory failure. Ventilators push air into and out of the patient’s lungs like a bellows, typically

through a tube that is connected to the machine on one end and inserted through the patient's nose or mouth into the trachea on the other end. Patients are typically sedated while on ventilation because it can otherwise cause intense pain. Ventilators can also be used in other circumstances, such as during surgery when general anesthesia may interrupt normal breathing. There are also ventilators for home use. The following image from the National Institute of Health shows a typical ventilator and how it works:



B. PHILIPS SOLD CPAP, BIPAP, AND VENTILATOR DEVICES CONTAINING PE-PUR FOAM.

71. Philips manufactures and sells CPAP and BiPAP machines and ventilators, among other products. According to Philips' 2020 Annual Report,⁹ Sleep & Respiratory Care constituted 49% of Philips' total sales in its Connected Care line of business, which in turn accounted for 28% of Philips' overall sales of about €19.535 billion (*i.e.*, \$22,541,631,850). Philips has sold millions of CPAP and BiPAP machines and ventilators in the United States.

72. The basic technology used in CPAP and BiPAP devices was developed in 1980 by an Australian pulmonologist, Dr. Colin Sullivan, who used it to treat dogs with respiratory problems, before the technology was adapted for humans.

73. Resironics commercialized this technology and sold the first publicly available CPAP device in 1985. ResMed, an industry competitor, followed with the release of its CPAP device in 1989.

74. These first-generation CPAP and BiPAP devices created a new and commercially viable field of respiratory therapy. The devices, however, were large and noisy, resulting in an “arms-race” between manufacturers to develop devices that were smaller, more responsive to patient breathing patterns, and quieter.

75. The noise level of CPAP and BiPAP devices became a driver of adult consumer preference because loud devices interrupt the peaceful sleep of both the patient and their partner, making it less likely that the patient will continue to use the device.

⁹

<https://www.results.philips.com/publications/ar20/downloads/pdf/en/PhilipsFullAnnualReport2020-English.pdf?v=20210531142942> (last accessed June 16, 2022).

76. Noise is also a problem in neonatal intensive care units where infants, especially those born premature, may remain on ventilators or CPAP or BiPAP devices for long periods.

77. To develop the quietest devices on the market with the lowest decibel ratings, device manufacturers such as Philips filled CPAP, BiPAP, and ventilator devices with sound abating foam to reduce the volume of noise emitted from the motor and airflow.

78. Since at least 2009, Philips has incorporated PE-PUR foam in its CPAP, BiPAP, and ventilator devices for sound abatement purposes.

79. In fact, the relative quiet of DreamStation products factored prominently into Philips' marketing.¹⁰ Philips put out information that it extensively studied and measured the amount of sound produced by DreamStation products. Philips even included an infographic indicating DreamStation products are barely louder than a whisper.

80. Polyurethane is an organic polymer in which urethane groups connect the molecular units and is usually formed by reacting a diisocyanate or triisocyanate with a polyol. Under certain circumstances, polyurethane may break down into a diisocyanate or triisocyanate as well.

81. The two main types of polyurethane are polyester and polyether. Polyester polyurethane has much better shock absorption and vibration dampening properties and is commonly used for soundproofing or sound dampening.

82. It has been known for decades that polyester polyurethane is subject to breakdown *via* hydrolysis, particularly in medical applications. For example, a chapter of a scientific encyclopedia published in 2013 states: "Poly(ester urethanes) were the first generation of PURs

¹⁰ See <https://www.documents.philips.com/assets/20170523/62e4f43a1349489ba3cca77c0169c6ef.pdf> (last accessed June 16, 2022).

used in medical devices but were found unsuitable for long-term implants because of rapid hydrolysis of the polyester soft segment[.]”¹¹

83. Polyether polyurethane, on the other hand, is less prone to breakdown *via* hydrolysis. The same encyclopedia chapter notes that polyether polyurethanes “with excellent hydrolytic stability replaced poly(ester urethanes) and have been used in medical devices for the past two decades.”¹²

84. All of the Philips Recalled Devices contain PE-PUR foam.

85. In the DreamStation Recalled Device, for example, there is a channel that surrounds the central fan in the device. The top of this channel is stuffed with PE-PUR foam to absorb the noise from the machine while the patient is sleeping. Air passes through this channel underneath the PE-PUR foam before it enters the fan and is pumped into the patient’s airway.

86. There were readily available alternatives available to Philips other than to use PE-PUR foam for sound abatement, including, without limitation, other types of sound abating foam.

87. One of Philips’ primary competitors, ResMed, primarily uses polyether polyurethane foam, not PE-PUR foam, for sound dampening.¹³

C. **PHILIPS KNEW OF THE DANGERS OF PE-PUR FOAM SINCE AT LEAST 2015**

88. The FDA has concluded that:

Beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the recalled devices, including

¹¹ Pal Singh Chauhan, N., and Kumari Jangid, N., “Polyurethanes and Silicone Polyurethane Copolymers,” Chapter in Encyclopedia of Biomedical Polymers and Polymeric Biomaterials, January 2013, available at <https://www.researchgate.net/publication/236144965>

POLYURETHANES AND SILICONE POLYURETHANE COPOLYMERS (last accessed June 16, 2022).

¹² *Id.*

¹³ <https://www.resmed.com/en-us/other-manufacturer-recall-2021/> (last accessed June 16, 2022).

complaints, test reports, information from suppliers, and information from another entity owned by Philips' parent company. Philips failed to adequately evaluate this data and incorporate it into its CAPA [Corrective and Preventive Actions] system for further investigation and potential mitigation, as required by current good manufacturing practice requirements codified in 21 C.F.R. § 820.100.¹⁴

89. The FDA's finding was based in part on twenty-one (21) site inspections of Philips' Murrysville, Pennsylvania facility between August 26, 2021 and November 9, 2021. The lead FDA investigator, Katelyn A. Staub-Zamperini, memorialized the agency's finding in a 28-page FDA-483 Report issued on November 9, 2021.¹⁵ The FDA delivered the 483 Report to Rodney Mell, Head of Quality at Philips Respiration, on or around November 9, 2021.¹⁶

90. A 483 Report "is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts."¹⁷ These observations are made in a 483 Report "when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been . . . or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health."¹⁸

91. In connection with its investigation for its 483 Report, the FDA learned that Philips had received numerous complaints from customers in the field about degradation of the foam in its Recalled Devices from at least as early as 2008:

¹⁴ <https://www.fda.gov/media/158129/download> ("518(b) Notice") at 6 (last accessed June 16, 2022).

¹⁵ A redacted version of the 483 report is available here: <https://www.fda.gov/media/154244/download> (last accessed June 16, 2022) ("483 Report").

¹⁶ *Id.* at 1, 28.

¹⁷ <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions> (last accessed June 16, 2022).

¹⁸ *Id.*

[A] query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, **resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 to 2017 and involved Trilogy devices.** Additionally, your firm performed a foam related complaint data analysis in April 2021 on complaints confirmed to be related to or involve foam degradation issues. The raw complaint data documents that **30 Trilogy related complaints were received from 2014 to 2017, and 1,254 related complaints were received across all products containing the affected foam, from 2014 to 2021.**¹⁹

92. Yet, “[n]o formal investigation, risk analysis, or CAPA were initiated, performed, or documented [by or on behalf of Philips], in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017 . . .”²⁰

93. A Corrective and Preventative Action (“CAPA”) refers to procedures that medical device manufacturers must follow to identify and attempt to correct when a quality problem is detected. *See* 21 C.F.R. § 820.100. A CAPA is designed “to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence.”²¹

94. The FDA also found that Philips “was made aware of polyester polyurethane foam degradation issues in/around October 2015 . . .”²²

95. In fact, an adverse event report from the FDA Manufacturer and User Facility Device Experience (“MAUDE”) database shows that, as early as 2011, Philips knew that a patient

¹⁹ 483 Report at 12 (emphasis added).

²⁰ *Id.* at 16.

²¹ <https://www.fda.gov/corrective-and-preventive-actions-capa> (last accessed June 16, 2022).

²² 483 Report at 18.

discovered “black dust” on her nose when she awoke after using a Philips RemStar CPAP device and subsequently underwent treatment for “intoxication” and “chest tightness.”²³

96. Philips investigated this report and confirmed that the device contained “evidence of an unk[nown] black substance in the air path and on internal components . . . present throughout both the intake and exhaust portions of the air path . . .”²⁴

97. Philips, however, stubbornly denied that the presence of the black substance was due to a product defect.

98. The FDA found that Philips’ analysis of consumer complaints was itself defective in that it “was not adequately performed to identify or detect quality problems.”²⁵ The FDA concluded that “potential foam degradation in Trilogy ventilator devices is not an isolated incident, and you [Philips] also have not documented a detailed rationale for why harm is not likely to occur again, as required by your Health Hazard Evaluation’s instructions.”²⁶ In light of this, the FDA concluded that Philips’ “risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of your firm becoming aware” of these issues.²⁷

99. On May 2, 2022, the FDA issued a formal notice to Philips pursuant to Section 518(b) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 360h(b) (the “518(b) Notice”).²⁸ The 518(b) Notice stated that the FDA’s “Center for Devices and Radiological Health

²³ MAUDE Adverse Event Report: RESPIRONICS, INC. REMSTAR PRO INTERNATIONAL, http://www.fda.gov/advanced_maude_query/324fd08a137ce36c2d5faf453ee26f2f (last accessed June 16, 2021).

²⁴ *Id.*

²⁵ 483 Report at 16.

²⁶ *Id.* at 13.

²⁷ *Id.* at 3.

²⁸ <https://www.fda.gov/media/158129/download> (last accessed June 16, 2022).

(CDRH) is proposing that an order should be issued pursuant to section 518(b)" of the FDCA "to require Philips to submit a plan for the repair, replacement, and/or refund of the purchase price of devices subject to the recall that were manufactured after November 2015, sufficient to assure that the unreasonable risk of substantial harm to the public health presented by those devices will be eliminated."²⁹ This notice was directed to Thomas J. Fallon, Head of Quality, Sleep and Respiratory Care, for Philips Respironics, Inc.

100. The 518(b) Notice stated that "there is sufficient evidence for FDA to determine that the devices subject to the recall present an unreasonable risk of substantial harm to the public health" and "that there are reasonable grounds to believe that the recalled devices that Philips manufactured after November 2015 were not properly manufactured with reference to the state of the art as it existed at the time of the devices' manufacture."³⁰

101. The 518(b) Notice also stated that "there is sufficient evidence for FDA to determine that there are reasonable grounds to believe that the risk associated with the devices was not caused by the failure of a person other than Philips to exercise due care in the installation, maintenance, repair, or use of the devices at issue" and specifically that "evidence indicates that the unreasonable risk associated with the products was not caused by the use of ozone cleaning agents, nor did the use of ozone to clean the products constitute a failure to exercise due care."³¹

102. The FDA concluded that "patients and providers cannot readily mitigate the unreasonable risk associated with the recalled devices[.]"³²

²⁹ 518(b) Notice at 1.

³⁰ *Id.* at 2.

³¹ *Id.*

³² *Id.*

103. The FDA also concluded that “[t]his risk is not the unavoidable byproduct of current ventilator, CPAP machine, and BiPAP machine technologies. Indeed, Philips and its competitors market ventilators, CPAP machines, and BiPAP machines that do not use PE-PUR foam.”³³

1. In 2015, Philips Communicated With Its Foam Suppliers About The Problem Of PE-PUR Foam Degradation.

104. The PE-PUR foam that Philips used in its Recalled Devices was manufactured by William T. Burnett & Co. (“Burnett”), a bulk foam manufacturer. Burnett produces foam in sheets that are between approximately four feet to more than six feet wide and may be as long as one hundred or two hundred feet.

105. Burnett sells its bulk foam to intermediaries, including PolyTech and SoundCoat. PolyTech and SoundCoat cut the foam down to a size suitable for use in a medical device. They then sell the foam to Philips, either directly or through another intermediary, Paramount Die, which may modify the foam further.

106. According to the FDA, “email correspondence between [Philips] and its raw foam supplier [PolyTech] beginning 10/30/2015 and forward, document that [Philips] was made aware of polyester polyurethane foam degradation issues in/around October 2015, which was later confirmed by [Philips’] foam supplier on 08/05/2016, via email.”³⁴

107. On August 5, 2016, Bob Marsh, a PolyTech employee, wrote to Lee Lawler, an employee of Burnett, referencing a concern expressed by one of its customers [Philips] in the Fall

³³ *Id.* at 6.

³⁴ 483 Report at 18.

of 2015 regarding foam degradation in its medical devices.³⁵ Mr. Marsh stated: “They [Philips] are asking again, and wondered if we could give them any estimate on lifespan of the foam when exposed to 40 C and high humidity.”³⁶ Mr. Lawler responded that, under those conditions, he “would not be surprised if ester foam . . . would exhibit signs of hydrolysis in as short a time as a year.”³⁷ He added that “that is not a good environment for polyester foam. Polyether foam could last years in that environment.”³⁸ Mr. Marsh responded that he would “let them [presumably Philips] know they’d be better off with the ether.”³⁹

108. Knowing about these issues with the PE-PUR foam, Philips tested the foam material used in its Recalled Devices. According to the FDA, “this testing spoke only to the limited finding that in the case of the [redacted] foam samples ‘returned from service in a Pacific rim location,’ spectroscopy results were ‘consistent with an environmental/chemical exposure causing base polymer cleavage and embrittlement of the material.’”⁴⁰ Nonetheless, based on the results of this limited testing, Philips concluded that no escalation to a CAPA process was required.

109. According to the FDA, “no further investigation, health hazard evaluation, risk analysis, or design review was performed or documented by Philips at that time . . . and no preventative maintenance procedures were implemented” other than a limited “preventative maintenance procedure” instituted by a “Philips . . . entity owned by the parent company of Philips

³⁵ See Email exchange between Bob Marsh at PolyTech and Lee Lawler at Burnett (Affidavit of Lee Lawler, Technical and R&D Manager at Burnett (“Lawler Aff.”) Exh. E, filed in MDL 3014, Case 2:21-mc-01230-JFC, at Doc. 589-7) (attached hereto as Exhibit “B”), at WTB 000056.

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ 518(b) Notice at 7.

Respironics” “to replace the air intake assembly of Trilogy ventilator products, due to complaints that had been received regarding degradation of the PE-PUR foam.”⁴¹ And even then, “Philips did not verify the effectiveness of this measure.”⁴²

110. Philips was alerted to more warning signs as it continued to ask its supplier about the properties of the PE-PUR foam it was continuing to put in medical devices that millions of its customers were breathing through daily.

111. Testing conducted for Philips in 2016 confirmed that Mr. Lawler from Burnett was correct. According to the FDA, this testing “determined that the PE-PUR foam was susceptible to degradation, resulting in the conclusion at that time that ‘polyester urethanes show bad resistance against high humidity in combination with high temperature.’”⁴³ Additional testing “determined that, compared to PE-PUR foam, another type of foam, polyether urethane, ‘show[s] a far better resistance against high humidity at high temperature.’”⁴⁴

112. The 483 Report identified “at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where [Philips] was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory care devices.”⁴⁵ It listed the specific analyses and tests, including one which concluded that “contrary to polyester urethane foams, [redacted] foams shows a far better resistance against high humidity at high temperature.”⁴⁶

⁴¹ *Id.* at 6-7.

⁴² *Id.* at 8.

⁴³ *Id.* at 7-8.

⁴⁴ *Id.* at 8.

⁴⁵ 483 Report at 3.

⁴⁶ *Id.* at 4.

113. Philips received at least 110 complaints confirmed to be related to foam degradation between 2014 and 2017.⁴⁷ Approximately 80 of these complaints concerned CPAP and BiPAP devices.⁴⁸

114. Nonetheless, Philips continued manufacturing and selling the now Recalled Devices containing PE-PUR foam.

2. Philips Opened An Internal Investigation Into Foam Degradation In Mid-2018 That Confirmed PE-PUR Foam Is Prone To Degradation.

115. On April 12, 2018, Philips opened a precursor to a formal CAPA, referred to by Philips as a CAPA INV 0988, “to investigate complaints related to potential foam degradation for the Trilogy devices in Australia and to determine what actions should be taken.”⁴⁹ Philips reported that “[u]nits were returned from the field where the Trilogy Removable Air Path Foam [redacted] and the foam in the Inlet Air Path Assembly [redacted] was degrading, and getting into the motor/air path, causing at least 1 Trilogy unit to fail.”⁵⁰

116. On April 20, 2018, Vincent Testa, a Project Mechanical Engineer at Philips, emailed Bonnie Peterson, Project Manager at PolyTech. Mr. Testa stated, “We use the PAFS foam in the air path of our Trilogy family of ventilators as a means for noise reduction . . .”⁵¹ PAFS foam is PolyTech’s open cell, flexible acoustical grade PE-PUR foam.⁵² Mr. Testa at Philips continued: “Recently weve [sic] received a few complaints from our customers that the foam is

⁴⁷ 518(b) Notice at 7.

⁴⁸ *Id.* at 8.

⁴⁹ *Id.*

⁵⁰ 483 Report at 14.

⁵¹ See Email from Vincent Testa at Philips to Bonnie Peterson at PolyTech (Lawler Aff. Exh. H, filed in MDL 3014, Case 2:21-mc-01230-JFC, at Doc. 589-10) (attached hereto as Exhibit “C”), at WTB 000070.

⁵² <https://www.polytechinc.com/products/acoustic-foam> (last accessed June 16, 2022).

disintegrating The material sheds and is pulled into the ventilator air path. As you can imagine, this is not a good situation for our users.”⁵³ Mr. Testa asked, “what could cause this material to break down.”⁵⁴

117. On April 23, 2018, Mr. Marsh from PolyTech forwarded Philips’ April 20, 2018 email to Mr. Lawler from Burnett, reporting that “[t]he customer [Philips] is finding degradation of the ester foam and the urethane film in their device, such that particles are breaking off and flowing in the airstream.”⁵⁵

118. On May 2, 2018, Mr. Marsh added in an email to Mr. Lawler that “Philips gave us another bit of information. They tested ether vs ester in high heat and humidity and found ether to be the better performer. It validated what we (you) had conveyed.”⁵⁶ Mr. Marsh asked whether exposure to oxygen, higher temperature, and higher humidity could accelerate deterioration of PE-PUR foam.⁵⁷

119. Mr. Lawler responded that he did “not believe that exposure to oxygen will cause any significant damage to polyurethane foam unless elevated temperature and/or humidity is also present.”⁵⁸

⁵³ See Email from Vincent Testa at Philips to Bonnie Peterson at PolyTech (Lawler Aff. Exh. H) (Exhibit “C” hereto), at WTB 000070.

⁵⁴ *Id.*

⁵⁵ See Email from Bob Marsh to Lee Lawler dated 4/23/2018 (Lawler Aff. Exh. H) (Exhibit “C” hereto), at WTB 000070.

⁵⁶ See Email from Bob Marsh to Lee Lawler dated 5/2/2018 (Lawler Aff. Exh. H) (Exhibit “C” hereto), at WTB 000069.

⁵⁷ *Id.*

⁵⁸ See Email from Lee Lawler to Bob Marsh dated 5/2/2018 (Lawler Aff. Exh. H) (Exhibit “C” hereto), at WTB 000069.

120. Mr. Testa from Philips admitted in a follow-up email to Bob Marsh from PolyTech on May 3, 2018, that:

We [Philips] are evaluating our options regarding the foam. We could switch to the PAF [ether-based foam], or we could indicate a preventative maintenance cycle in which they would replace the PAFS [ester-based] foam pieces. . . . The environmental conditions for our device are a maximum of 40C and 95% R.H. Note the difference in temperature.⁵⁹

121. Mr. Testa at Philips asked Bob Marsh from PolyTech the following:

1. Please ask your foam supplier to calculate the service life based on this higher temperature (40C vs. 27C).

a. It would also be useful if they could provide a graph depicting failure over time. For example, if tensile strength reduced over time, they would plot strength vs. time.

2. At the end of the service life, what is the failure mode of this material?⁶⁰

122. Mr. Marsh again forwarded these questions to Mr. Lawler at Burnett, who responded:

I am unable to answer Question Number 1. We would not recommend using **Polyester** foam in such an environment and have no direct data to use to calculate the rate of hydrolysis. **Polyether** foam lifetime would not be expected to reduce significantly at the stated conditions. Use with pure oxygen could shorten the lifetime some by promoting more rapid oxidation. I do not know the extent of the reduction, but do not expect it to be overly significant.

Polyester foam will lose tensile strength and overall integrity as it hydrolyzes. It will eventually decompose to a sticky powder. That will happen very rapidly at 40C, 95% R.H.⁶¹

⁵⁹ See Email from Vincent Testa to Bob Marsh dated 5/3/2018 (Lawler Aff. Exh. H) (Exhibit “C” hereto), at WTB 000068-69).

⁶⁰ *Id.*

⁶¹ See Email from Lee Lawler to Bob Marsh dated 5/4/2018 (Lawler Aff. Exh. H) (Exhibit “C” hereto), at WTB 000067-68.

123. Mr. Lawler from Burnett added: “Is it one of our data sheets that states foam lifetime being 10 years at 95% R.H? I do not think I have seen a sheet with that statement.”⁶² Mr. Marsh at PolyTech responded that he would pass along the information to Philips and that “[w]e have no idea where that statement came from. It has been on our data sheets for probably 20 years. We are removing it.”⁶³

124. On May 23, 2018, Mr. Marsh from PolyTech forwarded to Lee Lawler another question from Mr. Testa at Philips, about the degradation of the foam it was using in its Recalled Devices.⁶⁴ Mr. Testa explained that Philips had “sent samples to a local lab for analysis.”⁶⁵ The local lab concluded that the degradation was a result of cleavage of the bonds in the base polymer, and Mr. Testa stated that “[f]urther investigation concluded that prolonged exposure to high humidity causes the foam to degrade.”⁶⁶ Mr. Testa noted that “[a]s the foam degrades it breaks down into small particulate” and asked whether the foam “maintain[s] its UL 94 Flame Resistance rating if it is broken down into particulate?”⁶⁷

125. Mr. Lawler replied: “I am sure the degraded foam will not perform well in UL94 testing, though I cannot imagine how one would actually perform the test on such degraded material.”⁶⁸

⁶² *Id.* at WTB 000068.

⁶³ See Email from Bob Marsh at PolyTech to Lee Lawler at Burnett dated 5/4/2018 (Lawler Aff. Exh. H) (Exhibit “C” hereto), at WTB 000067.

⁶⁴ See Email from Bob Marsh to Lee Lawler dated 5/23/2018 (Lawler Aff. Exh. H) (Exhibit “C” hereto), at WTB 000066-67.

⁶⁵ *Id.* at WTB 000066.

⁶⁶ *Id.* at WTB 000067.

⁶⁷ *Id.*

⁶⁸ See Email from Lee Lawler to Bob Marsh dated 5/23/2018 (Lawler Aff. Exh. H) (Exhibit “C” hereto), at WTB 000066.

126. On June 7, 2018, Mr. Testa at Philips again emailed Mr. Marsh at PolyTech:

As we continue our investigation of the deterioration of the PAFS foam, a few questions has [sic] been posed regarding the material. Can you please reach out to your foam supplier regarding the following.

1. What is the actual composition of the polyurethane-ester foam PAFS-038? (CAS #s/percentages/weight percent/reactive groups etc. any chemistry is very appreciated)
2. What kind of diisocynate is used in the polyurethane foam synthesis process and how much?
3. Is diethylene glycol or another polyol utilized in the foam synthesis process?
4. Have you tested to see if all diisocyanate groups are reacted in your foam or are there unreacted groups even after manufacturing?⁶⁹

127. Mr. Marsh forwarded the questions to Mr. Lawler at Burnett, who asked why Mr. Testa needed this information. Mr. Marsh did not provide a definitive answer but said, “What Vince [Testa] told us is that they are investigating alternatives to polyurethane foam (ester and ether).”⁷⁰ Mr. Lawler ultimately did not answer Mr. Testa’s questions because they touched on Burnett’s confidential, proprietary information.

128. On June 20, 2018, Philips closed CAPA INV 0988.⁷¹ According to the FDA, Philips implemented “a preventative maintenance procedure for Trilogy devices, but Philips did not verify the effectiveness of this measure.”⁷² Yet “after CAPA INV 0988, Philips modified its CAPA procedures to include ‘requirements to help ensure that CAPAs are fully complete [and]

⁶⁹ See Email from Vincent Testa to Bob Marsh dated 6/7/2018 (Lawler Aff. Exh. I, filed in MDL 3014, Case 2:21-mc-01230-JFC, at Doc. 589-11) (attached as Exhibit “D” hereto), at WTB 000076-77.

⁷⁰ See Email from Bob Marsh to Lee Lawler dated 6/14/2018 (Lawler Aff. Exh. I) (Exhibit “D” hereto), at WTB 000075.

⁷¹ 483 Report at 15.

⁷² 518(b) Notice at 8.

appropriately scoped,’ and that ‘processing the issue [that was the subject of CAPA INV 0988] through the current CAPA program would have result[ed] in an appropriate horizontal assessment.’”⁷³

129. The FDA pointed out that Philips’ informal CAPA INV⁷⁴ related to these Trilogy devices did “not include, investigate, or examine all of your firm’s CPAP and BiPAP medical devices, which also include similar air path assemblies and/or the affected polyester polyurethane foam, which is susceptible to degradation.”⁷⁵ But Philips had acknowledged to the FDA that it had “received approximately eighty complaints related to foam degradation, **on non-Trilogy ventilator devices**, from 2014 to 2017.”⁷⁶

130. The FDA concluded that Philips had not “adequately established” procedures for initiating CAPA procedures.⁷⁷ Specifically, the FDA faulted Philips for not initiating a “formal” CAPA after receiving “various complaints alleging foam degradation in Trilogy ventilator devices” and then closing its informal investigation just two months later without “verify[ing] the effectiveness” of the limited “preventative maintenance procedure for Trilogy devices”⁷⁸

131. Philips continued to receive more information that suggested that the PE-PUR foam was prone to degradation. According to the FDA, “[a] follow-up email amongst your firm’s [Philips’] personnel, dated 08/24/2018, states that testing confirmed that the affected foam breaks

⁷³ *Id.*

⁷⁴ The Report explained that Philips’ practice at the time was to first open CAPA requests – called “CAPA INVs” – as a precursor to a formal CAPA, but this could only occur if approved by a “CAPA Review Board” or delegate. *See* 483 Report at 14-15.

⁷⁵ *Id.* at 15.

⁷⁶ *Id.* at 16 (emphasis supplied).

⁷⁷ *Id.* at 14.

⁷⁸ 518(b) Notice at 8.

down in high heat and high humidity environments, which concurred with Trilogy ventilator related complaints....”⁷⁹

132. Further, “[o]n December 12, 2018, several months after CAPA INV 0988 was closed, a report from additional testing conducted for Philips found that ‘[p]olyester polyurethane foam showed clear disintegration after 2 weeks.”⁸⁰

133. Nonetheless, Philips continued manufacturing and selling the Recalled Devices containing PE-PUR foam.

3. Philips Finally Opened A Formal CAPA In 2019 – But Did Not Initiate A Recall For Two More Years.

134. In April 2019, Philips received two complaints that “sound abatement foam ‘is degrading and entering the air path[.]’”⁸¹

135. In response, in June 2019, Philips finally initiated a formal CAPA, numbered CAPA 7211, related to the issues associated with the PE-PUR foam. But as the FDA explains:

Even then, that CAPA failed to evaluate all relevant data. Philips’ search of FDA’s Manufacturer and User Facility Device Experience (MAUDE) database in connection with CAPA 7211 identified only three medical device reports (MDRs) associated with potential foam degradation involving Trilogy ventilators between January 2011 and January 2021. Yet an MDR analysis conducted by Philips in 2018 had already identified 17 documented complaints related to foam degradation in Trilogy ventilators, and at least 14 of those 17 complaints had related MDRs. Similarly, Philips’ analysis of foam degradation-related complaints conducted in connection with CAPA 7211 identified 1,254 complaints confirmed to be related to foam degradation between 2014 and April 2021 across all affected products, yet this analysis failed to include several complaints confirmed to be related to foam degradation in Trilogy ventilators that were documented in 2018 in connection with CAPA INV 0988.⁸²

⁷⁹ 483 Report at 18.

⁸⁰ 518(b) Notice at 8.

⁸¹ *Id.*

⁸² *Id.* at 8-9.

136. Philips continued to test the PE-PUR foam while the CAPA was underway. A Biological Risk Assessment dated July 2, 2020, found that “the biological and toxicological risks from exposure to degraded PE-PUR foam are of concern....”⁸³

137. Another internal “Biological Risk Assessment” dated December 10, 2020 – and “conducted as a result of field reports/complaints regarding degraded sound abatement foam in various CPAP and ventilator products”⁸⁴ – described the risks that degraded polyurethane foam posed to humans in no uncertain terms:

The cytotoxicity and positive genotoxicity results observed from degraded PE-PUR foam samples **indicate a potential patient risk. Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure.** Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, **the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam.**⁸⁵

138. An additional Philips’ Biocompatibility Risk Assessment dated January 11, 2021, concurred that degraded PE-PUR foam “presents a significant biological risk to patients,” and goes on to state that “[p]otential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure.”⁸⁶

139. Ultimately, in CAPA 7211, Philips concluded that “the cause of the foam degradation condition is long-term exposure to environmental conditions of high temperature combined with high humidity” and restated that “the cause of degradation was due to chemical

⁸³ 483 Report at 7; *see also id.* (“Philips Respiration Inc. (PRI) was made aware in May 2019 that four CPAP units were returned to a service center with degraded sound abatement foam.”).

⁸⁴ *Id.* at 8.

⁸⁵ *Id.* at 7-8 (emphasis added).

⁸⁶ *Id.* at 8.

breakdown of the foam due to exposure to water caused by long-term exposure to environmental conditions.”⁸⁷

140. Based on its investigation, the FDA concluded that Philips’ upper management was aware of the foam degradation issues, discussed it at numerous management review meetings, and yet delayed doing anything about it:

[F]irm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021.

Polyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all [redacted] management review meetings, since the 2019 [redacted], dated 01/31/2020 Additionally, your firm [Philips] became aware of this issue and related field complaints in at least 2015 or earlier.⁸⁸

D. UNTIL THE RECALL, PHILIPS ADVERTISED ITS BREATHING MACHINES AS SAFE AND EFFECTIVE.

141. At no point prior to April 2021, when Philips first disclosed foam issues to its shareholders, did Philips even hint that there was a dangerous condition in its CPAP, BiPAP, and ventilator Recalled Devices. Instead, Philips held itself out as a trusted brand and “global leader in the sleep and respiratory markets.”⁸⁹ Its branding promises consumers that they will “[b]reath easier, sleep more naturally[.]”⁹⁰ Philips further assures consumers that its “sleep therapy systems are designed with the needs of care practitioners and patients in mind,” and that its “quality systems reflect [Philips’] commitment to providing enhanced patient comfort,” among other things. And it

⁸⁷ 518(b) Notice at 10.

⁸⁸ 483 Report at 24.

⁸⁹ http://www.respironics.com/product_library (last accessed June 16, 2022).

⁹⁰ *Id.*

has long advertised its CPAP and BiPAP Machines as “clinically proven” treatment for sleep disorders.⁹¹

142. Philips boasts that it has the “most prescribed CPAP systems by U.S. sleep physicians.”⁹² The CPAP and BiPAP machines routinely cost from seven or eight hundred dollars to thousands of dollars per machine, and the ventilators cost more than several thousands of dollars per machine.

E. PHILIPS BELATEDLY RECALLED ITS DEFECTIVE DEVICES CONTAINING PE-PUR FOAM DUE TO THE SERIOUS HEALTH HAZARDS THAT THEY CAUSE.

1. In April And May 2021, Philips Launched The DreamStation 2 And Tried To Convince Patients To Buy It, Without Initiating A Recall.

143. Two months prior to the Recall, Philips announced on April 13, 2021, that it was launching the DreamStation 2, a next-generation machine in its DreamStation product family. The DreamStation 2 does not contain PE-PUR foam.

144. Less than two weeks after its launch of the DreamStation 2, on April 26, 2021, Philips announced that its previous generation DreamStation products posed serious health risks to users and, in the same release, Philips started trying to convince consumers to purchase its DreamStation 2 device:

Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips’ sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone,* and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family. Philips’ recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this

⁹¹ See <https://www.usa.philips.com/healthcare/solutions/sleep> (last accessed June 16, 2022).

⁹² See <https://www.usa.philips.com/healthcare/solutions/sleep/sleep-therapy> (last accessed June 16, 2022) (citing 2016 Philips survey).

matter and initiating appropriate actions to mitigate these possible risks. Given the estimated scope of the intended precautionary actions on the installed base, Philips has taken a provision of EUR 250 million.⁹³

145. Philips' April 26, 2021 statement to investors did not disclose the full extent of its knowledge about the risks posed by the PE-PUR foam and attempted to deflect the blame on factors such as ozone cleaners. The FDA later rejected this notion, concluding that "*the unreasonable risk associated with the products was not caused by the use of ozone cleaning agents, nor did the use of ozone to clean the products constitute a failure to exercise due care.*"⁹⁴

146. Meanwhile, Philips continued to conduct tests that confirmed that its breathing products were defective.

147. For example, on May 17, 2021, Ken Cole from RJ Lee, an industrial forensics analytical laboratory and scientific consulting firm, produced a presentation analyzing the foam in Philips' Trilogy EVO devices. The presentation states that the investigation was "prompted by staff observation of color variance across both current production and previous builds."⁹⁵

148. The analysis involved six samples of foam, two from units built in 2018 and four taken from Philips' current production stock in May 2021.⁹⁶ Some of the samples from 2021 showed "differing cell structure" which is an "[i]ndication of poor process control."⁹⁷ The 2021

⁹³ <https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/phillips-first-quarter-results-2021.html> (last accessed June 16, 2022).

⁹⁴ 518(b) Notice at 10 (emphasis in original).

⁹⁵ See RJ Lee Analysis Review of Trilogy EVO Foam (Lawler Aff. Exh. A, filed in MDL 3014, Case 2:21-md-01230-JFC, at Doc. 589-3) (attached as Exhibit "E" hereto), at (WTB 000001-00003).

⁹⁶ *Id.* at WTB 000006.

⁹⁷ *Id.* at WTB 000008.

foam had “significant contaminants.”⁹⁸ The foam was supposed to be ether-based,⁹⁹ but testing revealed indications that some of the foam was actually ester-based.¹⁰⁰

2. In June 2021, Philips Finally Recalled Its Defective Devices.

149. Finally, on June 14, 2021, Philips issued a recall notice directed to its customers in the United States, stating:

To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device’s air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone,** and high heat and high humidity environments may also contribute to foam degradation.

Therefore, Philips has decided to voluntarily issue a recall notification* to inform patients and customers of potential impacts on patient health and clinical use related to this issue, as well as instructions on actions to be taken.¹⁰¹

150. Philips stated that “[t]he majority of the affected devices within the advised 5-year service life are in the first-generation DreamStation product family.”¹⁰² Philips elaborated:

Based on the latest analysis of potential health risks and out of an abundance of caution, the recall notification advises patients and customers to take the following actions:

For patients using affected BiLevel PAP and CPAP devices: Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician

⁹⁸ *Id.* at WTB 000009; *see also* WTB 000010 (“Indication of poor process control and/or contamination.”).

⁹⁹ *Id.* at WTB 000002.

¹⁰⁰ *Id.* at WTB 000013.

¹⁰¹ Recall Notices (Exhibit “A” hereto).

¹⁰² *Id.*

to determine if the benefit of continuing therapy with your device outweighs the risks identified in the recall notification.

For patients using affected life-sustaining mechanical ventilator devices: Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks identified in the recall notification.

Possible health risks

The company continues to monitor reports of potential safety issues as required by medical device regulations and laws in the markets in which it operates. To date, there have been no reports of death as a result of these issues. Philips has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects. Philips has received no reports regarding patient impact related to chemical emissions.¹⁰³

151. On the same day as the Recall, Philips provided additional information in an announcement entitled “Clinical information for physicians,” that explained that the foam breakdown “may lead to patient harm and impact clinical care.” It added the following:

While there have been limited reports of headache, upper airway irritation, cough, chest pressure and sinus infection that may have been associated with the foam, based on lab testing and evaluations, *it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.*¹⁰⁴

152. The announcement detailed two types of hazards from the foam in the devices.

First, the announcement described dangers due to foam degradation exposure:

¹⁰³ *Id.*

¹⁰⁴ Sleep and respiratory care update: Clinical information for physicians: [philips-recall-clinical-information-for-physicians-and-providers.pdf](https://www.philips.com/corporate/corporate-social-responsibility/sleep-and-respiratory-care-update-clinical-information-for-physicians-and-providers.pdf) (last accessed June 16, 2022) (emphasis added).

Potential Hazard: Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.

The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:

- Toluene Diamine
- Toluene Diisocyanate
- Diethylene glycol¹⁰⁵

153. Millions of patients across the United States, including all of the individual Named Plaintiffs, used and trusted the Recalled Devices. Philips has now revealed that the PE-PUR foam in their breathing machines degrades and exposes patients to toxic particles and gasses.

154. That the patients using the Recalled Devices were exposed to toxic and poisonous chemicals is not reasonably in dispute. According to the Report on Carcinogens, Fifteenth Edition, by the National Toxicology Program in the United State Department of Health and Human Services,¹⁰⁶ toluene diisocyanates are reasonably anticipated to be human carcinogens based on sufficient evidence of carcinogenicity from studies in experimental animals. Administration of commercial-grade toluene diisocyanate (analyzed as 85% 2,4 isomer and 15% 2,6 isomer) by stomach tube caused liver tumors (hepatocellular adenoma) in female rats and mice, benign tumors of the mammary gland (fibroadenoma) and pancreas (islet-cell adenoma) in female rats, and benign tumors of the pancreas (acinar-cell adenoma) in male rats. It also increased the combined

¹⁰⁵ *Id.*

¹⁰⁶ <https://ntp.niehs.nih.gov/ntp/roc/content/zip15.zip> (last accessed June 16, 2022).

incidences of benign and malignant tumors of subcutaneous tissue (fibroma and fibrosarcoma) in rats of both sexes and of the blood vessels (hemangioma and hemangiosarcoma) in female mice.

155. The Report also notes that toluene diisocyanates are used primarily to manufacture flexible polyurethane foams for use in furniture, bedding, and automotive and airline seats. The foam in Philips' Recalled Devices is flexible polyurethane foam.

156. Toluene diamine ("TDA") is classified by the United States Environmental Protection Agency ("EPA") as a probable human carcinogen. The EPA also determined that acute exposure to TDA can produce severe skin and eye irritation, sometimes leading to permanent blindness, respiratory problems (e.g., asthma), rise in blood pressure, dizziness, convulsions, fainting, and coma.

157. The European Union warns that toluene diisocyanate is "fatal if inhaled"¹⁰⁷ and has concluded that toluene diamine "cannot be considered safe for use" even as a hair dye, let alone breathed into the lungs for many hours each night.¹⁰⁸

158. Diethylene glycol ("DEG") is a widely used solvent, but there is limited information about its toxicity in humans, despite its historical involvement in mass poisonings around the world. Famously, DEG caused the death of 100 people across 15 states in the 1937 Elixir Sulfanilamide Incident, which served as a catalyst for the enactment of the Federal Food, Drug, and Cosmetic Act in 1938.¹⁰⁹

¹⁰⁷ <https://echa.europa.eu/substance-information/-/substanceinfo/100.043.369> (last accessed June 16, 2022).

¹⁰⁸ https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_093.pdf (last accessed June 16, 2022), at 5.

¹⁰⁹ <https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf> (last accessed June 16, 2022).

159. Philips disclosed that it “has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask).” The PE-PUR foam is black, and when it breaks down, it can release black particles.¹¹⁰

160. Philips concluded in its Health Hazard Evaluations (“HHEs”) regarding the foam degradation risk that “[b]ased on the cytotoxicity and genotoxicity results and toxicological risk assessment, combined with [the] conclusion that particles are likely to reach the upper airway and potentially the lower respiratory track, a reasonable worst-case estimate for the general and higher risk (e.g., patient populations with preexisting conditions or comorbidities) patient populations is a severity level 3 (Crucial) for both short/intermediate and long term exposure.”¹¹¹

161. Philips’ HHEs note that the harm due to foam degradation “‘may not be immediately recognizable and may not be something that the customer would/could report,’ adding that certain harms ‘may not be easily linked to the hazardous situation or device use in general’— and that in the case of genetic mutations in particular, ‘a presumed lag time from exposure to harm development may make it difficult for patients to attribute their individual harm to the device usage.’”¹¹²

162. The second hazard is the possibility of VOCs, that is, chemical emissions from the PE-PUR foam. Philips explained:

Potential Hazard: Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam

¹¹⁰ Sleep and respiratory care update: Clinical information for physicians: [philips-recall-clinical-information-for-physicians-and-providers.pdf](#) (last accessed June 16, 2022).

¹¹¹ 518(b) Notice at 3-4.

¹¹² *Id.* at 5.

included in the CPAP, BiLevel PAP and MV devices and may have short- and long-term adverse health effects.

Standard testing identified two compounds of concern (COC) may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:

- Dimethyl Diazine
- Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)-¹¹³

163. Philips admitted that the risks of these VOCs include: “irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve” and may lead to the following symptoms: “headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects,” as well as “adverse effects to other organs such as kidney and liver.”¹¹⁴

164. Corroborating the dangerous nature of the Recalled Devices, on July 22, 2021, the FDA upgraded Philips’ recall of the Recalled Devices to its most serious classification, Class I, which according to the FDA means: “A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.”¹¹⁵

165. Also, on June 14, 2021, Philips’ main competitor, ResMed, issued “[a] message from ResMed’s CEO” to the public regarding the Philips Recall. In this notice, ResMed CEO,

¹¹³ Sleep and respiratory care update: Clinical information for physicians: philips-recall-clinical-information-for-physicians-and-providers.pdf (last accessed June 16, 2022).

¹¹⁴ *Id.*

¹¹⁵ <https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions> (last accessed June 16, 2022).

Mick Farrell, stated that “ResMed devices are safe to use and are not subject to Philips’ recall. ResMed devices use a different material than what Philips uses in their recalled machines.”¹¹⁶

166. ResMed PAP devices and ventilators use polyether polyurethane or silicone-based foam for sound abatement purposes, not PE-PUR foam.¹¹⁷

167. On July 8, 2021, Philips released a global supplemental clinical information document that was based on their own testing of the affected devices, stating that, “According to analysis performed by Philips, the majority of particulates are of a size ($>8 \mu\text{m}$) . . . Smaller particulates ($<1-3 \mu\text{m}$) are capable of diffusing into deep lung tissue and deposit into the alveoli. During testing performed by an outside laboratory on lab degraded foam, the smallest particulate size identified was $2.69 \mu\text{m}$.¹¹⁸ The Environmental Protection Agency (EPA) notes that exposure to particles less than 10 micrometers can be linked to a variety of health problems including: aggravated asthma, decreased lung function, increased respiratory symptoms, and cardiac related diseases.”¹¹⁹

168. The purity of the air coming from a breathing device to a patient is highly important and material to a typical patient. Philips advertises the filtration systems in its devices, for example, noting them on a diagram in its DreamStation Family Brochure.¹²⁰ Philips’ filtration system, however, does not filter out the particles and VOCs described above.

¹¹⁶ <https://www.resmed.com/en-us/healthcare-professional/other-manufacturer-recall-2021/> (last accessed June 16, 2022).

¹¹⁷ <https://www.resmed.com/en-us/other-manufacturer-recall-2021/> (last accessed June 16, 2022).

¹¹⁸ Sleep and Respiratory Care update Clinical information (July 8, 2021), accessible at [philips-global-supplemental-clinical-information-document.pdf](https://www.philips-global-supplemental-clinical-information-document.pdf) (last accessed June 16, 2022).

¹¹⁹ <https://www.epa.gov/pm-pollution/health-and-environmental-effects-particulate-matter-pm> (last accessed June 16, 2022).

¹²⁰

<https://www.documents.philips.com/assets/20180205/15ef65ad106d4ddc88fca87e0134dc60.pdf?>

169. As noted here, Philips has admitted that the Recalled Devices are defective and unsafe. Plaintiffs and the Class have suffered injuries as a result of their purchase or lease of the Recalled Devices, including substantial economic losses related to their purchase or lease of the Recalled Devices and accessories, and replacement machines and accessories, and losses from not being able to use their machines, and other consequential damages.

F. PHILIPS' INEFFECTIVE MEASURES TO RECALL THE DEVICES

170. Philips' CEO, Frans van Houten, stated in the Recall announcement: "We deeply regret any concern and inconvenience that patients using the affected devices will experience because of the proactive measures we are announcing today to ensure patient safety."¹²¹

171. But Philips' "recall" was a recall in name only and did not effectively provide patients with notice of the risks of the Recalled Devices or with new Philips CPAP, BiPAP, or ventilator devices.

1. Many Patients, Providers, And Others Were Not Notified About The Recall.

172. On March 10, 2022, the FDA issued a Notification Order under § 518(a) of the FDCA.¹²² The Notification Order stated that the "FDA has received a number of calls from patients and consumers who contacted FDA to report problems and/or concerns regarding the Recalled

¹²¹ <https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html> (last accessed June 16, 2022).

¹²² <https://www.fda.gov/media/156811/download> (last accessed June 16, 2022).

Products, but were unaware of the recall and had not been informed of the health risks presented by the Recalled Devices.”¹²³

173. The FDA estimated that, after nine months of the Recall, “approximately 50% of patients and consumers who have purchased or received the Recalled Products (excluding ventilators) within the last five years (the service life of the devices) have registered with Philips to obtain a replacement device.”¹²⁴ But it was “unclear whether the remaining patients and consumers have not registered because they are unaware of the need to register, or because they do not want or need a replacement device from Philips.”¹²⁵

174. The FDA surveyed 182 consignees to determine whether they had been notified of the Recall and found 28 “who had reported to FDA that they were not aware of the recall.”¹²⁶ The FDA reported its results to Philips on September 8 and October 29, 2021, and Philips did not respond. On November 22, 2021, Philips stated that it had notified 23 of the 28 consignees of the Recall, but Philips did not “indicate whether the consignees identified by FDA had been sent notification before, or only after, they had been identified by FDA as being unaware of the recall.”¹²⁷ Moreover, Philips’ evidence of notification consisted of delivery confirmation receipts, reflecting that written correspondence was delivered to the consignees. As the FDA explained, “[t]ypically, firms demonstrate the effectiveness of its recall communications through evidence

¹²³ 518(a) Notification Order at 2.

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *Id.*

more meaningful than a delivery confirmation receipt, such as a returned response form or a documented telephone conversation.”¹²⁸

175. Throughout the Recall, the FDA “on multiple occasions has informed Philips that FDA was concerned that Philips’ efforts to notify patients and consumers, healthcare providers, and consignees regarding the recall have been insufficient” and has expressed concern that “it is likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products.”¹²⁹

176. Noting “Philips’ failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products,” the FDA issued an order under Section 518(a) of the FDCA ordering Philips to “notify all health professionals who prescribe or use the Recalled Products, and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products within the next 45 days[.]”¹³⁰

2. Philips’ Repair/Replacement Program Has Been Extremely Slow.

177. Those patients who registered their Recalled Devices with Philips for the Recall did not immediately receive replacement devices and were not told when a replacement device would be provided.

178. As Philips’ June 14, 2021 announcement explained:

Repair and replacement program

¹²⁸ *Id.* at 3.

¹²⁹ *Id.*

¹³⁰ *Id.* at 4 (emphasis in original).

Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances. Philips aims to address all affected devices in scope of this correction as expeditiously as possible.

As part of the program, the first-generation DreamStation product families will be modified with a different sound abatement foam and shipped upon receipt of the required regulatory clearances. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected by the issue. To support the program, Philips is increasing the production of its DreamStation 2 CPAP devices, that are available in the US and selected countries in Europe.¹³¹

179. In reality, patients may register their DreamStation Recalled Device with Philips for the Recall, but Philips has not immediately replaced the defective PE-PUR foam in the DreamStation Recalled Devices. Rather, patients have had to wait, sometimes for many months, for Philips to repair or replace their devices, and many patients are still waiting for a replacement device.

180. As of the date of this Complaint—about one year after the Recall was announced—Philips continues to repair or replace defective DreamStation 1 Recalled Devices. In other words, the Recall remains ongoing.

181. The replacement program for the Trilogy devices has been even slower. Philips has only just begun the rework of affected Trilogy 100/200 devices and Philips projects that the process will take approximately 12-14 months to complete.¹³²

182. There is no repair or replacement program for any of the other Recalled Devices recalled by Philips.

¹³¹ <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/philips-issues-recall-notification-mitigate-potential-health-risks-related-sound-abatement-foam> (last accessed June 16, 2022).

¹³² <https://www.usa.philips.com/healthcare/resource-catalog/landing/experience-catalog/sleep/communications/src-update/news/ventilation-news-and-updates> (last accessed June 16, 2022).

183. Due to the design of the Recalled Devices, it is prohibitively difficult for patients to remove or replace the PE-PUR foam themselves. Also, the FDA warns:

Do **not** try to remove the foam from your device. Trying to or successfully removing the foam may damage the device or change how the device works. It may also lead to more foam or chemicals entering the air tubing of the device.¹³³

184. As a result, the Recall leaves patients without safe, free options. Instead, patients may simply be forced to buy Philips' next-generation product or a competitor's product—at full price, and indeed, thousands of patients, including some of the Named Plaintiffs, have already done so.

185. Thus, Philips intends to, and is, simply profiting from its so-called “recall” by selling more of its next generation product, the DreamStation 2, to affected patients. It appears that Philips intentionally timed the “recall” to coincide with the launch of the DreamStation 2.

186. The FDA also believes that the Recall is not proceeding quickly enough. It recently stated:

Based on the status of Philips’ recall as of the date of this letter [May 2, 2022], CDRH believes that, if an order were to be issued to Philips under section 518(b), the plan submitted by Philips in response to that order should provide for significant improvements to Philips’ ongoing repair and replacement activities to speed the pace of remediation and address other deficiencies identified by CDRH and communicated to Philips, to the extent such improvements are achievable by Philips.¹³⁴

V. CLASS ALLEGATIONS

187. Plaintiffs bring this action individually and as a class action, pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3). Specifically, the Class consists of the following:

¹³³ <https://www.fda.gov/medical-devices/safety-communications/faqs-philips-respirronics-ventilator-bipap-machine-and-cpap-machine-recalls> (emphasis in original) (last accessed June 16, 2022).

¹³⁴ 518(b) Notice at 13.

Nationwide Class: All persons in the United States who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

188. Alternatively, and in addition, Plaintiffs seek certification on behalf of subclasses defined as more fully set forth below and collectively referred to as the “State Subclasses.”

189. Plaintiff Gothard seeks certification on behalf of a subclass defined as follows (“Alabama Subclass”):

Alabama Subclass: All persons in Alabama who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

190. Plaintiffs Groudan and Gilliard-Gunter seek certification on behalf of a subclass defined as follows (“Arizona Subclass”):

Arizona Subclass: All persons in Arizona who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

191. Plaintiffs Luenebrink and Waybright seek certification on behalf of a subclass defined as follows (“California Subclass”):

California Subclass: All persons in California who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

192. Plaintiffs Dzierzanowski, Fields, and Smith seek certification on behalf of a subclass defined as follows (“Florida Subclass”):

Florida Subclass: All persons in Florida who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

193. Plaintiff Fultz seeks certification on behalf of a subclass defined as follows (“Georgia Subclass”):

Georgia Subclass: All persons in Georgia who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

194. Plaintiff Diamond seeks certification on behalf of a subclass defined as follows (“Idaho Subclass”):

Idaho Subclass: All persons in Idaho who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

195. Plaintiffs Baran and Rootberg seek certification on behalf of a subclass defined as follows (“Illinois Subclass”):

Illinois Subclass: All persons in Illinois who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

196. Plaintiff Diane Anderson seeks certification on behalf of a subclass defined as follows (“Indiana Subclass”):

Indiana Subclass: All persons in Indiana who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

197. Plaintiff Ratliff seeks certification on behalf of a subclass defined as follows (“Kentucky Subclass”):

Kentucky Subclass: All persons in Kentucky who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

198. Plaintiffs Minnifield and Gilliard-Gunter seek certification on behalf of a subclass defined as follows (“Louisiana Subclass”):

Louisiana Subclass: All persons in Louisiana who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

199. Plaintiffs Julie Barrett, Peter Barrett, Margoles, and Schwartz seek certification on behalf of a subclass defined as follows (“Maine Subclass”):

Maine Subclass: All persons in Maine who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

200. Plaintiffs McGuire and Wilks seek certification on behalf of a subclass defined as follows (“Michigan Subclass”):

Michigan Subclass: All persons in Michigan who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

201. Plaintiff Tucker seeks certification on behalf of a subclass defined as follows (“Mississippi Subclass”):

Mississippi Subclass: All persons in Mississippi who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

202. Plaintiff Young seeks certification on behalf of a subclass defined as follows (“Missouri Subclass”):

Missouri Subclass: All persons in Missouri who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

203. Plaintiff David seeks certification on behalf of a subclass defined as follows (“Montana Subclass”):

Montana Subclass: All persons in Montana who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

204. Plaintiffs Dennis and Taylor seek certification on behalf of a subclass defined as follows (“New Jersey Subclass”):

New Jersey Subclass: All persons in New Jersey who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

205. Plaintiffs Diaz and Woodward seek certification on behalf of a subclass defined as follows (“New York Subclass”):

New York Subclass: All persons in New York who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

206. Plaintiff Margoles seeks certification on behalf of a subclass defined as follows (“North Carolina Subclass”):

North Carolina Subclass: All persons in North Carolina who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

207. Plaintiffs Flick, Fultz, Giordano, Hock, and Stefanini seek certification on behalf of a subclass defined as follows (“Ohio Subclass”):

Ohio Subclass: All persons in Ohio who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

208. Plaintiff Mcelyea seeks certification on behalf of a subclass defined as follows (“Oklahoma Subclass”):

Oklahoma Subclass: All persons in Oklahoma who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

209. Plaintiffs Julie Barrett and Peter Barrett seek certification on behalf of a subclass defined as follows (“Oregon Subclass”):

Oregon Subclass: All persons in Oregon who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

210. Plaintiff Masington seeks certification on behalf of a subclass defined as follows (“Pennsylvania Subclass”):

Pennsylvania Subclass: All persons in Pennsylvania who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

211. Plaintiffs William Anderson and Diaz seek certification on behalf of a subclass defined as follows (“South Carolina Subclass”):

South Carolina Subclass: All persons in South Carolina who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

212. Plaintiffs Deleon, Lowney, Panzera, and Polk seek certification on behalf of a subclass defined as follows (“Texas Subclass”):

Texas Subclass: All persons in Texas who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

213. Plaintiff Matters seeks certification on behalf of a subclass defined as follows (“Wisconsin Subclass”):

Wisconsin Subclass: All persons in Wisconsin who purchased, otherwise acquired, or leased a Recalled Device but did not resell it.

214. Together, the Nationwide Class and the Subclasses shall be collectively referred to herein as the “Class.” Excluded from the Class are Defendants and their employees, officers, and directors; and the Judge(s) assigned to this case.

215. Plaintiffs reserve the right to adjust, modify, or narrow the Class prior to class certification.

216. The rights of each member of the Class were violated in a similar fashion based upon Defendants’ uniform actions.

217. This action has been brought and may be properly maintained as a class action for the following reasons:

a. Numerosity: Members of the Class are so numerous that their individual joinder is impracticable. The proposed Class contains at least millions of individuals who purchased, otherwise acquired, or leased a Recalled Device. The Class is therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class members is unknown to Plaintiffs at this time, but the Class members are readily ascertainable and can be identified by Defendants’ records and records of third parties, such as durable medical equipment providers.

b. Existence and Predominance of Common Questions of Fact and Law: Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class members. These common legal and factual questions include, without limitation:

- i. Whether Defendants were unjustly enriched by the sale of Recalled Devices;
- ii. Whether Defendants failed to warn consumers regarding the risks of the Recalled Devices;
- iii. Whether the Recalled Devices suffer from a design defect;

- iv. Whether Philips violated express or implied warranties in selling the Recalled Devices;
- v. Whether Philips' practices constitute unfair or deceptive acts or practices under state consumer protection statutes;
- vi. The appropriate nature of class-wide equitable relief;
- vii. The appropriate measurement of restitution and/or measure of damages to Plaintiffs and members of the Class;
- viii. The appropriate measure of statutory damages; and
- ix. Whether Plaintiffs are entitled to punitive damages.

These and other questions of law or fact which are common to the members of the Class predominate over any questions affecting only individual members of the Class.

c. Typicality: Plaintiffs' claims are typical of the claims of all members of the Class.

d. Adequacy: Plaintiffs are adequate representatives of the Class because their interests do not conflict with the interests of the Class that they seek to represent; they have retained counsel competent and highly experienced in complex class action litigation and they intend to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiffs and their counsel.

e. Superiority: A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiffs and the Class. The injury suffered by each Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments.

Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

VI. EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

218. The running of any statute of limitations has been equitably tolled by Defendants' fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Philips actively concealed from Plaintiffs and their physicians the true risks associated with the Recalled Devices.

219. As a result of Defendants' actions, Plaintiffs were unaware, and could not have reasonably known or learned through reasonable diligence, that they had been exposed to the risks and harms set forth here and that those risks and harms were the direct and proximate result of Defendants' acts and omissions.

VII. CAUSES OF ACTION

COUNT I BREACH OF EXPRESS WARRANTY On behalf of the Nationwide Class and all Subclasses

220. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

221. Philips warranted that all of the Recalled Devices "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale."¹³⁵

¹³⁵ See, e.g., Warranty Exemplars: Dreamstation (attached hereto as Exhibit "F-1"), at 29; REMstar SE (attached hereto as Exhibit "F-2"), at 21; Trilogy 100 (attached hereto as Exhibit "F-3"), at 163.

222. Philips breached its express warranty in connection with the sale and distribution of Recalled Devices. At the point of sale, the Recalled Devices, while appearing normal, contained latent defects as set forth here, rendering them unsuitable and unsafe for personal use.

223. Had Plaintiffs and the Class known the Recalled Devices were unsafe for use, they would not have purchased them.

224. Philips has breached their warranty and refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Devices were safe for their ordinary and intended use.

225. To the extent privity may be required, Plaintiffs and the Class can establish privity with Philips or alternatively, Plaintiffs can establish that they fall into an exception to a privity requirement. Plaintiffs and the Class relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

226. Alternatively, Plaintiffs and the Class were foreseeable third-party beneficiaries of Philips sale of the Recalled Devices.

227. Plaintiffs are not required to give notice to Philips, a remote manufacturer and Philips has had notice of the type and source of claims in this matter for nearly a year.

228. Philips has refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiffs and the Class reasonably expected, at the time of purchase, that the Recalled Devices were safe for their ordinary and intended use.

229. As a direct and proximate result of Philips' breach of its express warranty, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

COUNT II
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
On behalf of the Nationwide Class and all Subclasses

230. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

231. By operation of law, Philips, as the manufacturer of the Recalled Devices and as the providers of a limited warranty for the Recalled Devices, impliedly warranted to Plaintiffs and the Class that the Recalled Devices were of merchantable quality and safe for their ordinary and intended use.

232. Such implied warranty of merchantability, contained in U.C.C. § 2-314, has been codified in each state.

233. Philips breached the implied warranty of merchantability in connection with the sale and distribution of the Recalled Devices. At the point of sale, the Recalled Devices, while appearing normal, contained latent defects as set forth here rendering them unsuitable and unsafe for personal use.

234. Philips breached the implied warranty of merchantability in connection with the sale and distribution of the Recalled Devices. At the point of sale, the Recalled Devices, while appearing normal, contained latent defects as set forth here rendering them unsuitable and unsafe for personal use.

235. Had Plaintiffs and the Class known the Recalled Devices were unsafe for use, they would not have purchased or leased them.

236. To the extent privity may be required, Plaintiffs and the Class can establish privity with Philips or alternatively, Plaintiffs can establish that they fall into an exception to a privity

requirement. Plaintiffs and the Class relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

237. Alternatively, Plaintiffs and the Class were foreseeable third-party beneficiaries of Philips sale of the Recalled Devices.

238. Plaintiffs are not required to give notice to Philips, a remote manufacturer and Philips has had notice of the type and source of claims in this matter for nearly a year.

239. Philips has refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiffs and the Class reasonably expected, at the time of purchase, that the Recalled Devices were safe for their ordinary and intended use.

240. As a direct and proximate result of Philips' breach of the implied warranty of merchantability, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

COUNT III
BREACH OF THE IMPLIED WARRANTY OF USABILITY
On behalf of the Nationwide Class and all Subclasses

241. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

242. By operation of law, Philips, as the manufacturer of the Recalled Devices and as the providers of a limited warranty for the Recalled Devices, impliedly warranted to Plaintiff and the Class that the Recalled Devices were usable for their ordinary and intended use.

243. Such implied warranty arises under U.C.C. § 2-314(3) as adopted in each state.

244. Through usage of trade, manufacturers of prescription drugs and medical devices impliedly warrant that their products are usable for the end consumer.

245. Philips breached the implied warranty of usability in connection with the sale and distribution of the Recalled Devices. At the point of sale, the Recalled Devices while appearing normal—contained defects as set forth herein rendering them unusable.

246. Philips, its agents and employees knew or should have known that the Recalled Devices suffer from a defect that causes negative health effects and/or places persons at risk for negative health effects to such an extent that the products are unusable.

247. Philips' Recall announcement instructed Class members to not use Recalled Devices because of the health risks. This renders the products unusable and thus worthless.

248. Philips has refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Devices were usable for their ordinary and intended use.

249. To the extent privity may be required, Plaintiffs and the Class can establish privity with Philips or alternatively, Plaintiffs can establish that they fall into an exception to a privity requirement. Plaintiffs and the Class relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

250. Alternatively, Plaintiffs and the Class were foreseeable third-party beneficiaries of Philips sale of the Recalled Devices.

251. Plaintiffs are not required to give notice to Philips, a remote manufacturer and Philips has had notice of the type and source of claims in this matter for nearly a year.

252. Had Plaintiff and Class members known they would not be able to use their Recalled Devices, they would not have purchased them or would have paid significantly less for them.

253. As a direct and proximate result of Philips' breach of the implied warranty of usability, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT IV
FAILURE TO WARN
On behalf of the Nationwide Class and all Subclasses

254. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

255. Defendants had a duty to warn Plaintiffs and the Class members regarding the defect and true risks associated with the Recalled Devices.

256. Defendants failed to provide adequate warnings regarding the risks of the PE-PUR foam.

257. Defendants had information regarding the true risks but failed to warn Plaintiffs, Class members, and their physicians to strengthen their warnings.

258. Despite Defendants' obligation to unilaterally strengthen the warnings, Philips instead chose to actively conceal this knowledge.

259. Plaintiffs and the Class members would not have purchased, chosen, and/or paid for all or part of the Recalled Devices if they knew of the defect and the risks of purchasing the product.

260. Defendants owed Plaintiffs and Class Members a duty of care and to warn of any risks associated with the Recalled Devices. Defendants knew or should have known of the true risks but failed to warn Plaintiffs, Class members, and their doctors.

261. This defect proximately and Defendants' negligent breach of its duties caused Plaintiffs' and Class members' injuries which include economic injuries, as well as headache,

irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

262. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT V
DESIGN DEFECT
On behalf of the Nationwide Class and all Subclasses

263. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

264. Defendants negligently designed the Recalled Products. Philips owed Plaintiff and the Class a duty to design the Recalled Products in a reasonable manner.

265. The design of the Recalled Products, including but not limited to design and use of the PE-PUR foam and the placement of the foam within the Recalled Products, was defective and unreasonably dangerous, causing degradation and inhalation of the PE-PUR foam, and causing headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

266. The design of the Recalled Products and the PE-PUR foam rendered the Recalled Products not reasonably fit, suitable, or safe for their intended purpose.

267. The dangers of the Recalled Products outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are other CPAP and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestions.

268. Safer alternative machines were available that did not suffer from the defect as set forth herein and that did not have an unreasonable risk of harm as with the Recalled Products and their unsafe PE-PUR foam, for example machines made by other manufacturers.

269. The risk benefit profile of the Recalled Products was unreasonable, and the

products should have had stronger and clearer warnings or should not have been sold in the market.

270. The Recalled Products did not perform as an ordinary consumer would expect.

271. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT VI
COMMON LAW FRAUD
On Behalf of the Nationwide Class and all Subclasses

272. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

273. Philips knew that the Recalled Devices posed serious health risks to users.

274. Philips failed to advise Plaintiff and the Class of the material fact that the Recalled Devices posed serious health risks to users. Philips concealed information regarding the adverse health effects posed by the Recalled Devices from Plaintiffs and the Class members. Philips misrepresented to Plaintiffs and the Class members that the Recalled Devices were safe for use.

275. Philips was under a duty to disclose to Plaintiffs and the Class members the serious health risks posed to users because: (a) Philips was in a superior position to Plaintiffs and the Class members to know the risks associated with the use of the Recalled Devices; (b) Philips was in a superior bargaining position to Plaintiffs and the Class members in determining whether or not to disclose or conceal information regarding the Recalled Devices in its packaging, labels, advertising, and websites; (c) Philips made representations regarding the safety of the Recalled Devices and had a duty to fully disclose all facts related to the serious health risks to users posed by the Recalled Devices, once Philips became aware of such serious health risks; (d) Philips knew that the Plaintiffs and the Class members could not reasonably have been expected to learn or discover the serious health risks posed by use of the Recalled Devices prior to purchasing the Recalled Devices, given the representations, concealed material information, and omissions by

Philips in its packaging, labels, advertising, and websites; and (e) Philips has a duty to disclose information related to the health and safety of its products.

276. Philips intentionally, knowingly, and recklessly allowed its packaging, labels, advertisements, promotional materials, and websites to mislead Plaintiffs and the Class members to believe that the Recalled Devices were safe for use.

277. Philips knew that its omissions, concealment, and representations in its packaging, labels, advertisements, promotional materials, and websites regarding the Recalled Devices were false, deceptive, inadequate, and misleading, and that the Recalled Devices contained PE-PUR Foam and thus could cause adverse health effects to users of the Recalled Devices.

278. Philips concealed and misrepresented material information regarding the serious health risks posed to users of the Recalled Devices from Plaintiffs and the Class members, by failing to include material information in its packaging, labels, advertisements, promotional materials, and websites.

279. The information undisclosed and concealed by Philips to Plaintiffs and the Class members were material, as a reasonable consumer would find information regarding serious adverse health risks associated with the use of the Recalled Devices important when deciding whether to purchase the Recalled Devices.

280. As a result of such deceptive packaging, labels, advertisements, promotional materials, and websites, Plaintiffs and the Class members justifiably and reasonably believed the Recalled Devices were safe for use.

281. Philips intentionally, knowingly, and recklessly made these material omissions and misrepresentations, and concealed material information regarding the adverse health risks associated with the Recalled Devices in its packaging, labels, advertisements, promotional

materials, and websites regarding the Recalled Devices to induce Plaintiffs and the Class members to purchase the Recalled Devices.

282. Plaintiffs and the Class members relied on Philips' deceptive packaging, labels, advertisements, promotional materials, and websites and purchased and used the Recalled Devices to their detriment. Given the deceptive manner in which Philips advertised, represented, and promoted the Recalled Devices, such reliance by Plaintiffs and the Class members was reasonable and justified.

283. As a direct and proximate result of Philips' material omissions, misrepresentations, and concealment of material information regarding the adverse health effects to users of the Recalled Devices, Plaintiffs and the Class members have suffered actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages.

COUNT VII
UNJUST ENRICHMENT (in the alternative)
On behalf of the Nationwide Class and all Subclasses

284. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

285. Plaintiffs and Class members conferred a tangible and material economic benefit upon Philips by purchasing the Recalled Devices. Plaintiffs and Class members would not have purchased or paid for the Recalled Devices had they known the true risks of using the Recalled Devices.

286. Philips readily accepted and retained these benefits. Philips profited from the sale of the Recalled Devices to the detriment and expense of Plaintiffs and Class members.

287. Philips appreciated these benefits. These benefits were the expected result of Philips acting in its pecuniary interest at the expense of their customers. Philips knew of these benefits because Philips was aware of the defective nature of the Recalled Devices; Philips failed to disclose this knowledge, and thereby misled Plaintiffs and Class members regarding the nature and quality of the Recalled Devices while profiting from this deception.

288. Under these circumstances, it would be unjust, inequitable, and unconscionable for Philips to retain the economic benefits it received at the expense of Plaintiffs and the Class, including because they were procured as a result of Philips' wrongful conduct alleged above. Failing to require Philips to provide remuneration under these circumstances would result in Philips being unjustly enriched at the expense of Plaintiffs and Class members who endure being exposed to the risk of developing serious medical conditions and can no longer use their machines safely.

289. Philips' retention of the benefits conferred upon it by Plaintiffs and the Class would be unjust and inequitable.

290. Plaintiffs are entitled to restitution of the benefits Philips unjustly retained and/or any amounts necessary to return Plaintiffs to the position they occupied prior to dealing with Philips, such amounts to be determined at trial.

291. Plaintiffs plead this claim separately as well as in the alternative to their other claims, as without such claims they would have no adequate legal remedy.

292. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT VIII
MEDICAL MONITORING
On behalf of the Nationwide Class and all Subclasses

293. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

294. At all relevant times, the Defendants designed, manufactured, assembled, inspected, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the Recalled Devices into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that used them, such as Plaintiffs.

295. Defendants have reported that users of the Recalled Devices face risks of serious injury from the degradation of PE-PUR Foam contained in the Recalled Devices. Degradation of PE-PUR Foam may be caused by exposure to chemical emissions from the foam material, high heat and high humidity environments.

296. When PE-PUR Foam degrades into particles that may enter the device's pathway and be ingested or inhaled by users of the devices, users face significantly increased risks of serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. The potential risks of degraded foam exposure include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects.

297. The off-gassing of chemicals from the PE-PUR Foam contained in the Recalled Devices poses risks of serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. The potential risks of

exposure to off-gassing from PE-PUR Foam include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

298. The absence of visible particles does not mean that PE-PUR Foam breakdown has not already begun. Philips has reported that lab analysis of the degraded foam reveals the presence of harmful chemicals including: TDA, TDI, and DEG. TDI is a powerful irritant to the mucous membranes of the eyes and gastrointestinal and respiratory tracts, and has been reported to cause Occupational Asthma. Exposure to TDA may result in ataxia, tachycardia, nausea, vomiting, convulsions, and respiratory depression. TDA can cause chemical cyanosis (*i.e.*, bluish discoloration of the skin) by converting hemoglobin to methemoglobin. This compound can also cause fatty degeneration of the liver. TDA and TDI are potential carcinogens. Repeated exposure to DEG has been associated with damage to the kidneys and renal failure.

299. As a direct and proximate result of Defendants' conduct, Plaintiffs have been exposed to substantially increased risks of serious injury from off-gassing and/or degradation of PE-PUR Foam in the Recalled Devices, which is beyond normal background levels of risk.

300. As a direct and proximate result of Defendants' conduct, Plaintiffs have a significantly increased risk of suffering serious injury or contracting a serious latent disease, and suffering further injury at an unknown date in the future. Such injuries include cancer and organ failure, among others currently unknown or just being discovered.

301. Monitoring procedures exist that makes the early detection of damage from degraded and/or off-gassed PE-PUR Foam possible. These procedures are different from that normally recommended in the absence of the exposure. These monitoring procedures include non-routine surveillance studies, laboratory testing, and physical examinations, and would be reasonably necessary according to contemporary scientific principles.

302. Existing medical research indicates that exposure to TDI, TDA, and DEG, which Philips has found to exist in off-gassed or degraded PE-PUR Foam, can cause serious, life-threatening and permanent injuries. Philips has received reports from users of the Recalled Devices of headache, upper airway irritation, cough, chest pressure and sinus infection. The exposure to the defects inherent in the Recalled Devices has occurred for users, such as Plaintiffs, but the full extent of the injuries will not manifest until later in the Plaintiffs' life. Thus, because of Defendants' conduct, it is reasonably necessary that Plaintiffs be placed under period diagnostic testing beyond that normally recommended in the absence of use of the Recalled Devices.

303. Plaintiffs demand judgment against Defendants for medical monitoring damages to diagnose injuries caused by the Recalled Devices at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IX
Alabama Deceptive Trade Practices Act
Ala. Code §§ 8-19-1, et seq.
On Behalf of the Alabama Subclass

304. Plaintiff Gothard realleges and incorporates by reference all preceding allegations as though fully set forth herein.

305. Plaintiff Gothard brings this cause of action individually and on behalf of the members of the Alabama Subclass.

306. The Alabama Deceptive Trade Practices Act ("ADTPA") was created to protect Alabama consumers from deceptive and unfair business practices.

307. Philips' conduct described herein constitutes a violation of several of the provisions enumerated in Ala. Code § 8-19-5, including but not limited to: misrepresentations as to a product's characteristics; misrepresentations as to a product's standard or style; advertising goods

with intent not to sell as advertised, and engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

308. Plaintiff and Alabama Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Ala. Code § 8-19-5. Plaintiff and Alabama Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

309. Accordingly, pursuant to Ala. Code § 8-19-10(a)(1), Plaintiff and Alabama Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Alabama Subclass members are entitled to all available statutory, exemplary, treble and/or punitive damages based on the nature of the violation of the ADTPA and the factors in Ala. Code § 8-19-10(a)(2), and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

310. To the extent that any pre-suit notice was purportedly required, Philips has had notice of its violations for nearly a year. Further, at a minimum on October 28, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter

complying with any required pre-suit notification requirements. Philips has failed to remedy its unlawful conduct.

COUNT X
Arizona Consumer Fraud Act
Ariz. Rev. Stat. §§ 44-1521, *et seq.*
On Behalf of the Arizona Subclass

311. Plaintiffs Groudan and Gilliard-Gunter reallege and incorporate by reference all preceding allegations as though fully set forth herein.

312. Plaintiffs Groudan and Gilliard-Gunter bring this cause of action individually and on behalf of the members of the Arizona Subclass.

313. The Arizona Consumer Fraud Act was created to protect Arizona consumers from deceptive and unfair business practices.

314. Philips' conduct described herein constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Arizona, making it unlawful under Ariz. Rev. Stat. § 44-1522(A).

315. Plaintiffs and Arizona Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Ariz. Rev. Stat. § 44-1522(A). Plaintiffs and Arizona Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

316. Accordingly, pursuant to Ariz. Rev. Stat. § 44-1528(A), Plaintiffs and Arizona Subclass members are entitled to recover their actual damages, which can be calculated with a

reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and Arizona Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XI

California Unfair Competition Law

Cal. Bus. & Prof. Code §§ 17200, *et seq.* (Unfair and Fraudulent Prongs)
On Behalf of the California Subclass

317. Plaintiffs Luenebrink and Wayright reallege and incorporate by reference all preceding allegations as though fully set forth herein.

318. Plaintiffs Luenebrink and Waybright bring this cause of action individually and on behalf of the members of the California Subclass.

319. California Business & Professions Code § 17200 ("UCL") prohibits acts of "unfair competition," including any "unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising."

320. The acts and practices of Philips as alleged herein constitute "unfair" business acts and practices under the UCL in that Philips' conduct is unconscionable, immoral, deceptive, unfair, illegal, unethical, oppressive, and/or unscrupulous. Further, the gravity of Philips' conduct outweighs any conceivable benefit of such conduct.

321. Philips has, in the course of its business and in the course of trade or commerce, undertaken and engaged in unfair business acts and practices under the UCL by concealing the true risks of the Recalled Devices.

322. These acts also constitute “fraudulent” business acts and practices under the UCL in that Philips’ conduct is false, misleading, and has a tendency to deceive California Subclass members and the general public.

323. Plaintiffs and California Subclass members have suffered injury in fact and have lost money as a result of Philips’ fraudulent business acts or practices.

324. The above-described unfair business acts or practices present a threat and likelihood of harm and deception to Plaintiffs and California Subclass members in that Philips has systematically perpetrated the unfair conduct upon members of the public by engaging in the conduct described herein.

325. Pursuant to Business and Professions Code §§ 17200 and 17203, Plaintiffs and California Subclass members seek an order providing restitution and disgorgement of all profits relating to the above-described unfair business acts or practices, and injunctive and declaratory relief as may be appropriate.

326. Because of their reliance on Philips’ omissions concerning the Recalled Devices, Plaintiffs and California Subclass members suffered an ascertainable loss of money, property, and/or value and were harmed and suffered actual damages.

327. Plaintiffs and California Subclass members are reasonable consumers who did not expect the risks inherent with the Recalled Devices.

328. Philips’ conduct in concealing and failing to disclose the true risks of the Recalled Devices is unfair in violation of the UCL, because it is immoral, unethical, unscrupulous,

oppressive, and substantially injurious.

329. Philips acted in an immoral, unethical, unscrupulous, outrageous, oppressive, and substantially injurious manner.

330. The gravity of harm resulting from Philips' unfair conduct outweighs any potential utility. The practice of selling Recalled Devices that present a substantial health risk to consumers harms the public at large and is part of a common and uniform course of wrongful conduct.

331. The harm from Philips' conduct was not reasonably avoidable by consumers because only Philips was aware of the true facts concerning the risks of its Recalled Devices, and Philips did not disclose them, despite knowing of such defects. Plaintiffs and California Subclass members did not know of and had no reasonable means of discovering the true risk of using the Recalled Devices.

332. Plaintiffs and California Subclass members suffered injury in fact, including lost money or property, as a result of Philips' unfair acts. Absent Philips' unfair conduct, Plaintiffs would not have bought the Recalled Devices.

333. Through their unfair conduct, Philips acquired money that Plaintiffs and California Subclass members once had ownership of.

334. Plaintiffs and California Subclass members accordingly seek appropriate relief under the UCL, including (a) restitution in full and (b) such orders or judgments as may be necessary to enjoin Philips from continuing their unfair practices.

COUNT XII
California Unfair Competition Law
Cal. Bus. & Prof. Code §§ 17200, et seq. (Unlawful Prong)
On Behalf of the California Subclass

335. Plaintiffs Luenebrink and Waybright reallege and incorporate by reference all preceding allegations as though fully set forth herein.

336. Plaintiffs Luenebrink and Waybright bring this cause of action individually and on behalf of the members of the California Subclass.

337. The UCL prohibits any “unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising.” Cal. Bus. & Prof. Code § 17200 (“UCL”). By engaging in business practices which are also illegal, Philips have violated the UCL.

338. Philips’ “unlawful” acts and practices include its breach of express warranty, breach of the implied warranty of merchantability, breach of implied warranty of usability, failure to warn, design defect, fraud-based omissions, and unjust enrichment.

339. More specifically, Philips breached applicable warranties in connection with the sale and distribution of the Recalled Devices. Philips sold the Recalled Devices to Plaintiffs and the California Subclass members, knowing that they were defective and could cause serious health problems. Philips further refused to provide appropriate warranty relief in connection with the Recalled Devices, despite knowing that these medical devices are vital to Plaintiffs and California Subclass members’ health.

340. Plaintiffs and California Subclass members conferred tangible and material economic benefits upon Philips by purchasing the Recalled Devices. Plaintiffs and California Subclass members would not have purchased the Recalled Devices had they known the associated risks, or that Philips would refuse to appropriately repair or replace the devices.

341. Plaintiffs and California Subclass members hold a property interest and right to possession in their respective Recalled Devices. Plaintiffs and California Subclass members have a legal interest in their ability to safely use these medical devices and to have their Recalled Devices appropriately repaired or replaced. Philips’ actions violated these interests and rights.

342. Philips reaped unjust profits, revenue, and benefits by virtue of their UCL violations. Plaintiffs and California Subclass members seek restitutionary disgorgement of these unjust profits and revenues.

COUNT XIII
California Consumers Legal Remedies Act
Cal. Civ. Code §1750, *et seq.*
On Behalf of the California Subclass

343. Plaintiffs Luenebrink and Waybright reallege and incorporate by reference all preceding allegations as though fully set forth herein.

344. Plaintiffs Luenebrink and Waybright bring this cause of action individually and on behalf of the members of the California Subclass.

345. The California Consumer Legal Remedies Act (“CLRA”) protects California consumers from deceptive and unfair trade practices.

346. Philips’ conduct described herein constitutes the knowing act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in California, and was made by Philips with knowledge of the serious health risks associated with use of the Recalled Devices and with the intention that Plaintiffs and California Subclass members would rely on such conduct in purchasing the Recalled Devices, making it unlawful under Cal. Civ. Code §1750, *et seq.*

347. Plaintiffs and California Subclass members relied on the material representations made by Philips and purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Cal. Civ. Code §1750, *et seq.* Plaintiffs and California Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips’

unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

348. Accordingly, pursuant to Cal. Civ. Code §1750, *et seq.*, Plaintiffs and California Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and California Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

349. To the extent that any pre-suit notice was purportedly required, Philips has had notice of its violations for nearly a year. Further, at a minimum on October 28, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. Philips has failed to remedy its unlawful conduct.

COUNT XIV
California False Advertising Law
Cal. Bus. & Prof. Code § 17500, *et seq.*
On Behalf of the California Subclass

350. Plaintiffs Luenebrink and Waybright reallege and incorporate by reference all preceding allegations as though fully set forth herein.

351. Plaintiffs Luenebrink and Waybright bring this cause of action individually and on behalf of the members of the California Subclass.

352. The California False Advertising Law (“FAL”) was created to protect California consumers from deceptive and unfair business practices.

353. Philips’ conduct described herein constitutes the knowing act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in California, making it unlawful under Cal. Bus. & Prof. Code § 17500, *et seq.*

354. Plaintiffs and California Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Cal. Bus. & Prof. Code § 17500, *et seq.* Plaintiffs and California Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips’ unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

355. Accordingly, pursuant to Cal. Bus. & Prof. Code § 17500, *et seq.*, Plaintiffs and California Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips’ conduct, Plaintiffs and California Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys’ fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips’ unlawful conduct.

COUNT XV
Florida Deceptive and Unfair Trade Practices Act
Fla. Stat. Ann. § 501.201 *et seq.*
On Behalf of the Florida Subclass

356. Plaintiffs Dzierzanowski, Fields, and Smith reallege and incorporate by reference all preceding allegations as though fully set forth herein.

357. Plaintiffs Dzierzanowski, Fields, and Smith bring this cause of action individually and on behalf of the members of the Florida Subclass.

358. The Florida Deceptive and Unfair Trade Practices Act was created to protect Florida consumers from deceptive and unfair business practices.

359. Philips' conduct described herein constitutes use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Florida, making it unlawful under Fla. Stat. Ann. § 501.201 *et seq.*

360. Plaintiffs and Florida Subclass members relied on the material representations made by Philips and purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Fla. Stat. Ann. § 501.201, *et seq.* Plaintiffs and Florida Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

361. Accordingly, pursuant to Fla. Stat. Ann. § 501.201 *et seq.*, Plaintiffs and Florida Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid

and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and Florida Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XVI
Florida False Advertising Statute
Fla. Stat. Ann. §§817.06, 817.41 *et seq.*
On Behalf of the Florida Subclass

362. Plaintiffs Dzierzanowski, Fields, and Smith reallege and incorporate by reference all preceding allegations as though fully set forth herein.

363. Plaintiffs Dzierzanowski, Fields, and Smith bring this cause of action individually and on behalf of the members of the Florida Subclass.

364. The Florida False Advertising Statute was created to protect Florida consumers from deceptive and unfair advertising practices.

365. Philips' conduct described herein constitutes use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression and omission of material facts in connection with the advertisement of merchandise, the Recalled Devices, in trade or commerce in Florida and was made with the intention that Plaintiffs and Florida Subclass members rely on such advertisements in purchasing the Recalled Devices, making it unlawful under Fla. Stat. Ann. § 817.06 and §817.41, *et seq.*

366. Plaintiffs and Florida Subclass members relied on the material representations made by Philips and purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act

or practice declared unlawful by Fla. Stat. Ann. § 817.06 and § 817.41, *et seq.* Plaintiffs and Florida Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

367. Accordingly, under Fla. Stat. Ann. § 817.06 and §817.41, *et seq.*, Plaintiffs and Florida Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and Florida Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XVII
Georgia Uniform Deceptive Trade Practices Act
Ga. Code. Ann. §10-1-370, *et seq.*
On Behalf of the Georgia Subclass

368. Plaintiff Fultz realleges and incorporates by reference all preceding allegations as though fully set forth herein.

369. Plaintiff Fultz brings this cause of action individually and on behalf of the members of the Georgia Subclass.

370. The Georgia Uniform Deceptive Trade Practices Act was created to protect Georgia consumers from deceptive and unfair business practices.

371. Philips' conduct described herein constitutes use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Georgia, making it unlawful under Ga. Code. Ann. §10-1-370, *et seq.*

372. Plaintiff and Georgia Subclass members relied on the material representations made by Philips and purchased the Recalled Devices for personal purposes and have suffered and will continue to suffer ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Ga. Code. Ann. §10-1-370, *et seq.* Plaintiff and Georgia Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that has resulted and will continue to result in damages to Plaintiff and Georgia Subclass members.

373. Accordingly, pursuant to Ga. Code. Ann. §10-1-370, *et seq.*, Plaintiff and Georgia Subclass members are entitled to equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XVIII
Georgia Fair Business Practices Act
Ga. Code. Ann. §10-1-390, *et seq.*
On Behalf of the Georgia Subclass

374. Plaintiff Fultz realleges and incorporates by reference all preceding allegations as though fully set forth herein.

375. Plaintiff Fultz brings this cause of action individually and on behalf of the members of the Georgia Subclass.

376. The Georgia Fair Business Practices Act ("GFBPA") was created to protect Georgia consumers from deceptive and unfair business practices.

377. Philips' conduct described herein constitutes use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Georgia, making it unlawful under Ga. Code. Ann. §10-1-390, *et seq.*

378. Plaintiff and Georgia Subclass members relied on the material representations made by Philips and purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Ga. Code. Ann. §10-1-390, *et seq.* Plaintiff and Georgia Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

379. Accordingly, pursuant Ga. Code. Ann. §10-1-390, *et seq.*, Plaintiff and Georgia Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Georgia Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

380. To the extent that any pre-suit notice was purportedly required, Philips has had notice of its violations for nearly a year. Further, at a minimum on October 28, 2021, and on May

16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. Philips has failed to remedy its unlawful conduct.

COUNT XIX
Idaho Consumer Protection Act
Idaho Code §48-601, *et seq.*
On Behalf of the Idaho Subclass

381. Plaintiff Diamond realleges and incorporates by reference all preceding allegations as though fully set forth herein.

382. Plaintiff Diamond brings this cause of action individually and on behalf of the members of the Idaho Subclass.

383. The Idaho Consumer Protection Act was created to protect Idaho consumers from deceptive and unfair business practices.

384. Philips' conduct described herein constitutes use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Idaho, making it unlawful under Idaho Code §48-601, *et seq.*

385. Plaintiff and Idaho Subclass members relied on the material representations made by Philips and purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Idaho Code §48-601, *et seq.* Plaintiff and Idaho Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

386. Accordingly, pursuant to Idaho Code §48-601, *et seq.*, Plaintiff and Idaho Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Idaho Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XX
Illinois Consumer Fraud and Deceptive Business Practices Act
815 Ill. Comp. Stat. Ann. §505/1, *et seq.*
On Behalf of the Illinois Subclass

387. Plaintiffs Baran and Rootberg reallege and incorporate by reference all preceding allegations as though fully set forth herein.

388. Plaintiffs Baran and Rootberg bring this cause of action individually and on behalf of the members of the Illinois Subclass.

389. The Illinois Consumer Fraud and Deceptive Business Practices Act was created to protect Illinois consumers from deceptive and unfair business practices.

390. Philips' conduct described herein constitutes use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Illinois, with the intention that Plaintiffs and Illinois Subclass members

would rely on such conduct in deciding to purchase the Recalled Devices, making it unlawful under 815 Ill. Comp. Stat. Ann. §505/1, *et seq.*

391. Plaintiffs and Illinois Subclass members relied on the material representations made by Philips and purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by 815 Ill. Comp. Stat. Ann. §505/1, *et seq.* Plaintiffs and Illinois Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

392. Accordingly, pursuant to 815 Ill. Comp. Stat. Ann. §505/1, *et seq.*, Plaintiffs and Illinois Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and Illinois Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XXI
Illinois Uniform Deceptive Trade Practices Act
815 Ill. Comp. Stat. Ann. §5105/1, *et seq.*
On Behalf of the Illinois Subclass

393. Plaintiffs Baran and Rootberg reallege and incorporate by reference all preceding allegations as though fully set forth herein.

394. Plaintiffs Baran and Rootberg bring this cause of action individually and on behalf of the members of the Illinois Subclass.

395. The Illinois Uniform Deceptive Trade Practices Act was created to protect Illinois consumers from deceptive and unfair advertising practices.

396. Philips' conduct described herein constitutes use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Illinois, with the intention that Plaintiffs and Illinois Subclass members would rely on such advertisements in deciding to purchase the Recalled Devices, making it unlawful under 815 Ill. Comp. Stat. Ann. §5105/1, *et seq.*

397. Plaintiffs and Illinois Subclass members relied on the material representations made by Philips and purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by 815 Ill. Comp. Stat. Ann. §5105/1, *et seq.* Plaintiffs and Illinois Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

398. Accordingly, Plaintiffs and the Illinois Subclass members are entitled to equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XXII
Indiana Deceptive Consumer Sales Act
Ind. Code §24-5-0.5-1, *et seq.*
On Behalf of the Indiana Subclass

399. Plaintiff Diane Anderson realleges and incorporates by reference all preceding allegations as though fully set forth herein.

400. Plaintiff Diane Anderson brings this cause of action individually and on behalf of the members of the Indiana Subclass.

401. The Indiana Deceptive Consumer Sales Act was created to protect Indiana consumers from deceptive and unfair business practices.

402. Philips' conduct described herein constitutes the knowing use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Indiana, making it unlawful under Ind. Code §24-5-0.5-1, *et seq.*

403. Plaintiff and Indiana Subclass members relied on the material representations made by Philips and purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Ind. Code §24-5-0.5-1, *et seq.* Plaintiff and Indiana Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

404. Accordingly, pursuant to Ind. Code §24-5-0.5-1, *et seq.*, Plaintiff and Indiana Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Indiana Subclass members are entitled to all available

statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

405. To the extent that any pre-suit notice was purportedly required, Philips has had notice of its violations for nearly a year. Further, at a minimum on October 28, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. Philips has failed to remedy its unlawful conduct.

COUNT XXIII
Kentucky Consumer Protection Act
Ky. Rev. Stat. §367.110, *et seq.*
On Behalf of the Kentucky Subclass

406. Plaintiff Ratliff realleges and incorporates by reference all preceding allegations as though fully set forth herein.

407. Plaintiff Ratliff brings this cause of action individually and on behalf of the members of the Kentucky Subclass.

408. The Kentucky Consumer Protection Act was created to protect Kentucky consumers from deceptive and unfair business practices.

409. Philips' conduct described herein constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Kentucky, making it unlawful under Ky. Rev. Stat. §367.110.

410. Plaintiff and Kentucky Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use

or employment of a method, act or practice declared unlawful by Ky. Rev. Stat. §367.110. Plaintiff and Kentucky Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

411. Accordingly, pursuant to Ky. Rev. Stat. §367.110, Plaintiff and Kentucky Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Kentucky Subclass members are entitled to all available statutory exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XXIV
REDHIBITION
(Including Warranty of Fitness)
Pursuant to La. Civ. Code art. 2520, *et seq.*
On behalf of the Louisiana Subclass

412. Plaintiffs Minnifield and Gilliard-Gunter reallege and incorporate by reference all preceding allegations as though fully set forth herein.

413. Plaintiffs Minnifield and Gilliard-Gunter bring this cause of action individually and on behalf of the members of the Louisiana Subclass.

414. At all times herein, Philips was the manufacturer of the Recalled Devices sold to Plaintiffs.

415. At the time the Recalled Devices were sold and/or delivered to Plaintiffs herein, Philips had reason to know and were in fact aware that Plaintiffs and Louisiana Subclass members intended to use the devices to treat sleep apnea or for other reasons related to breathing.

416. The devices manufactured, distributed and/or sold by Philips were not reasonably fit for their ordinary and intended use and purpose.

417. Philips is therefore liable to Plaintiffs and Louisiana Subclass members for all damages reasonable in the premises, in accordance with La. Civ. Code art. 2524.

418. The Recalled Devices manufactured, distributed and/or sold by Philips contained redhibitory defects at the time of sale and/or delivery, including the propensity to degrade and/or emit potentially harmful substances, as described above.

419. The Recalled Devices manufactured, distributed and/or sold by Philips contained redhibitory defects at the time of sale and/or delivery that render the devices so useless and/or inconvenient that it must be presumed that Plaintiffs and Louisiana Subclass members would not have purchased the devices had they known of the redhibitory defects.

420. In the alternative, the redhibitory defects diminish the Recalled Devices' use and/or value to such an extent that it must be presumed that Plaintiffs and Louisiana Subclass members would have bought them, but for a lesser price.

421. Philips is conclusively presumed to know of the defects in the Recalled Devices it manufactured.

422. In addition, it is believed and alleged that Philips knew of the Defect in the devices at the time the Recalled Devices were sold and/or delivered to Plaintiffs and Louisiana Subclass members, and as such Philips is considered to be a seller in bad faith.

423. The defective condition affecting the Recalled Devices was present at the time of their sale and/or delivery to Plaintiffs and Louisiana Subclass members.

424. The defective condition affecting the Recalled Devices was neither known nor could have been discovered by Plaintiffs at the time the Recalled Devices were sold and/or delivered to them.

425. As a result of Philips' Recalled Devices' redhibitory defects, Plaintiffs and Louisiana Subclass members have suffered actual damages in that each Recalled Device they purchased is worth less than the price they paid and which they would not have purchased at all had they known of the health risks associated with the use of the Recalled Devices.

426. In addition, because Philips was aware at the time the Recalled Devices were sold and/or delivered to Plaintiffs and Louisiana Subclass members that Plaintiffs intended to use the Recalled Devices to treat sleep apnea or for other reasons related to breathing and that the Recalled Devices were not fit for Plaintiffs' particular purposes, Philips breached the contract of sale in bad faith.

427. Philips is therefore liable to Plaintiffs and Louisiana Subclass members for a return of the purchase price (with interest from the time it was paid), insurance co-payments, reimbursement of reasonable expenses occasioned by the sale and those incurred for the preservation of the Recalled Devices and associated items, for damages, including any and all economic damages, cost of procuring a replacement device, mental anguish, fear and fright, inconvenience, and/or loss of use, and for reasonable attorneys' fees, in accordance with La. Civ. Code art. 2545.

COUNT XXV
Louisiana Unfair Trade Practices and Consumer Protection Law
La. Rev. Stat. Ann. §51:1401, *et seq.*
On Behalf of the Louisiana Subclass

428. Plaintiffs Minnifield and Gilliard-Gunter reallege and incorporate by reference all preceding allegations as though fully set forth herein.

429. Plaintiffs Minnifield and Gilliard-Gunter bring this cause of action individually and on behalf of the members of the Louisiana Subclass.

430. The Louisiana Unfair Trade Practices and Consumer Protection Law (“LUPTA”) was created to protect Louisiana consumers from deceptive and unfair business practices.

431. Philips’ conduct described herein constitutes the knowing and willful act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Louisiana, and was made with the intention that Plaintiffs and Louisiana Subclass members would rely upon such conduct in purchasing the Recalled Devices, making it unlawful under La. Rev. Stat. Ann. §51:1401.

432. Plaintiffs and Louisiana Subclass members relied on the material representations made by Philips and purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by La. Rev. Stat. Ann. §51:1401. Plaintiffs and Louisiana Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips’ unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

433. Accordingly, pursuant to La. Rev. Stat. Ann. §51:1401, Plaintiffs and Louisiana Subclass members are entitled to recover their actual damages, which can be calculated with a

reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and Louisiana Subclass members are entitled to all available statutory exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XXVI
Maine Unfair Trade Practices Act
5 Me. Rev. Stat. Ann. §§205-A, *et seq.*
On Behalf of the Maine Subclass

434. Plaintiffs Julie Barrett, Peter Barrett, Margoles, and Schwartz reallege and incorporate by reference all preceding allegations as though fully set forth herein.

435. Plaintiffs Julie Barrett, Peter Barrett, Margoles, and Schwartz bring this cause of action individually and on behalf of the members of the Maine Subclass.

436. The Maine Unfair Trade Practices Act was created to protect Maine consumers from deceptive and unfair business practices.

437. Philips' conduct described herein constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Maine, making it unlawful under 5 Me. Rev. Stat. Ann §205-A.

438. Plaintiffs and Maine Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use

or employment of a method, act or practice declared unlawful by 5 Me. Rev. Stat. Ann §205-A. Plaintiffs and Maine Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

439. Accordingly, pursuant to 5 Me. Rev. Stat. Ann §205-A, Plaintiffs and Maine Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and Maine Subclass members are entitled to all available statutory exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

440. To the extent that any pre-suit notice was purportedly required, Philips has had notice of its violations for nearly a year. Further, at a minimum on October 28, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. Philips has failed to remedy its unlawful conduct.

COUNT XXVII
Maine Uniform Deceptive Trade Practices Act
10 Me. Rev. Stat. tit. §1211, *et seq.*
On Behalf of the Maine Subclass

441. Plaintiffs Julie Barrett, Peter Barrett, Margoles, and Schwartz reallege and incorporate by reference all preceding allegations as though fully set forth herein.

442. Plaintiffs Julie Barrett, Peter Barrett, Margoles, and Schwartz bring this cause of action individually and on behalf of the members of the Maine Subclass.

443. The Maine Uniform Deceptive Trade Practices Act was created to protect Maine consumers from deceptive and unfair business practices.

444. Philips' conduct described herein constitutes the act, use or employment of conduct in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Maine, which conduct created confusion or misunderstanding on the part of Plaintiffs and Maine Subclass Members, making it unlawful under 10 Me. Rev. Stat. tit. §1121.

445. Plaintiffs and Maine Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by 10 Me. Rev. Stat. tit. §1121. Plaintiffs and Maine Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

446. Accordingly, Plaintiffs and the Maine Subclass members are entitled to equitable relief necessary or proper to protect them from Philips' unlawful conduct and to award all appropriate damages and attorneys' fees and costs.

COUNT XXVIII
Michigan Consumer Protection Act
Mich. Comp. Laws Ann. §445.901, *et seq.*
On Behalf of the Michigan Subclass

447. Plaintiffs McGuire and Wilks reallege and incorporate by reference all preceding allegations as though fully set forth herein.

448. Plaintiffs McGuire and Wilks bring this cause of action individually and on behalf of the members of the Michigan Subclass.

449. The Michigan Consumer Protection Act was created to protect Michigan consumers from deceptive and unfair business practices.

450. Philips' conduct described herein constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Michigan, made with the intention that Plaintiffs and Michigan Subclass members would rely upon such conduct in purchasing the Recalled Devices, making it unlawful under Mich. Comp. Law Ann. §445.901, *et seq.*

451. Plaintiffs and Michigan Subclass members relied upon the material representations made by Philips and purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Mich. Comp. Law Ann. §445.901, *et seq.*

452. Plaintiffs and Michigan Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

453. Accordingly, pursuant to Mich. Comp. Law Ann. §445.901, *et seq.*, Plaintiffs and Michigan Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and Michigan Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the

amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XXIX
Mississippi Consumer Protection Act
Miss. Code §75-24-1, *et seq.*
On Behalf of the Mississippi Subclass

454. Plaintiff Tucker realleges and incorporates by reference all preceding allegations as though fully set forth herein.

455. Plaintiff Tucker brings this cause of action individually and on behalf of the members of the Mississippi Subclass.

456. The Mississippi Consumer Protection Act ("MCPA") was created to protect Mississippi consumers from deceptive and unfair business practices.

457. Philips' conduct described herein constitutes the knowing and willful act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression and omission of material facts in connection with the advertisement and sale of merchandise, the Recalled Devices, in trade or commerce in Mississippi, making it unlawful under Miss. Code §75-24-1, *et seq.*

458. Plaintiff and Mississippi Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Miss. Code §75-24-1, *et seq.*

459. Plaintiff and Mississippi Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

460. Accordingly, pursuant to Miss. Code §75-24-1, *et seq.*, Plaintiff and Mississippi Subclass members are entitled to recover their actual damages, which can be calculated with a

reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Mississippi Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

461. To the extent that any pre-suit notice was purportedly required, Philips has had notice of its violations for nearly a year. Further, at a minimum on October 28, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements and invited Philips to engage in the alternative dispute resolution process with the Mississippi Attorney General. Philips has failed to remedy its unlawful conduct.

COUNT XXX
Missouri Merchandising Practices Act
Mo. Rev. Stat. § 407.010, *et seq.*
On Behalf of the Missouri Subclass

462. Plaintiff Young realleges and incorporates by reference all preceding allegations as though fully set forth herein.

463. Plaintiff Young brings this cause of action individually and on behalf of the members of the Missouri Subclass.

464. The Missouri Merchandising Practices Act ("MMPA") was created to protect Missouri consumers from deceptive and unfair business practices.

465. Philips' conduct described herein constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Missouri, making it unlawful under Mo. Rev. Stat. § 407.020.

466. Plaintiff and Missouri Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Mo. Rev. Stat. § 407.020. Plaintiff and Missouri Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

467. Accordingly, pursuant to Mo. Rev. Stat. § 407.025, Plaintiff and Missouri Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Missouri Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XXXI
Montana Unfair Trade Practices and Consumer Protection Act
Mont. Code §30-14-101, *et seq.*
On Behalf of the Montana Subclass

468. Plaintiff David realleges and incorporates by reference all preceding allegations as though fully set forth herein.

469. Plaintiff David brings this cause of action individually and on behalf of the members of the Montana Subclass.

470. The Montana Unfair Trade Practices and Consumer Protection Act was created to protect Montana consumers from deceptive and unfair business practices.

471. Philips' conduct described herein constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the advertisement and sale of merchandise, the Recalled Devices, in trade or commerce in Montana, making it unlawful under Mont. Code §30-14-101, *et seq.*

472. Plaintiff and Montana Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Mont. Code §30-14-101, *et seq.*

473. Plaintiff and Montana Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

474. Accordingly, pursuant to Mont. Code §30-14-101, *et seq.*, Plaintiff and Montana Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid

and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Montana Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XXXII
VIOLATIONS OF THE NEW JERSEY CONSUMER FRAUD ACT
N.J. Stat. Ann. §§56:8-1, et seq. ("CFA")
On Behalf of the New Jersey Subclass

475. Plaintiffs Dennis and Taylor reallege and incorporate by reference all preceding allegations as though fully set forth herein.

476. Plaintiffs Dennis and Taylor bring this action individually and on behalf of the members of the New Jersey Subclass.

477. The New Jersey Consumer Fraud Act ("CFA") was created to protect New Jersey consumers from fraudulent business practices.

478. Philips has knowingly engaged in deceptive, unconscionable, unlawful, unfair, false, fraudulent and misleading commercial practices, including misleading omissions of material fact, in connection with the marketing, promotion and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

479. Plaintiffs and New Jersey Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by N.J. Stat. Ann. §56:8-2. Plaintiffs and New Jersey Subclass members acted as reasonable consumers would have acted under the

circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

480. Accordingly, pursuant to the aforementioned statutes, Plaintiffs and New Jersey Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and New Jersey Subclass members are entitled to recover statutory, exemplary, treble, and/or punitive damages, together with interest, cost of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

COUNT XXXIII
**VIOLATIONS OF THE NEW YORK DECEPTIVE ACTS
OR PRACTICES AND FALSE ADVERTISING**
N.Y. Gen. Bus. Law §349; §350
On Behalf of the New York Subclass

481. Plaintiffs Diaz and Woodward reallege and incorporate by reference all preceding allegations as though fully set forth herein.

482. Plaintiffs Diaz and Woodward bring this action individually and on behalf of the members of the New York Subclass.

483. The N.Y. Gen. Bus. Laws were created to protect New York consumers from fraudulent business practices and false advertising.

484. Philips unfairly engaged in deceptive, unconscionable, unlawful, unfair, false, fraudulent and misleading commercial practices, including misleading omissions of material fact,

in connection with the marketing, promotion and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

485. Plaintiffs and New York Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by N.Y. Gen. Bus. Law §§349; 350. Such deceptive method, act or practice was material to Plaintiffs and the New York Subclass' decision to purchase the Recalled Devices, as reasonable consumers would have acted under the circumstances, thereby resulting in such damages.

486. Accordingly, pursuant to the aforementioned laws, Plaintiffs and New York Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and New York Subclass members are entitled to recover statutory, exemplary, treble, and/or punitive damages, together with interest, cost of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

COUNT XXXIV
**VIOLATIONS OF THE NORTH CAROLINA UNFAIR AND DECEPTIVE TRADE
 PRACTICES ACT (“UDTPA”)**
N.C. Gen. Stat. §§75-1, *et seq.*
On Behalf of the North Carolina Subclass

487. Plaintiff Margoles realleges and incorporates by reference all preceding allegations as though fully set forth herein.

488. Plaintiff Margoles brings this action individually and on behalf of the members of the North Carolina Subclass.

489. The North Carolina Unfair and Deceptive Trade Practices Act (“UDTPA”) was created to protect North Carolina consumers from unfair or deceptive business practices.

490. Philips has engaged in immoral, unethical, oppressive, unscrupulous, substantially injurious and misleading commercial practices, with the intent to deceive the consumer in connection with the marketing, promotion and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

491. Plaintiff and North Carolina Subclass members reasonably relied on the actions by Philips when they purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property, due to these unfair and deceptive act and practices. Plaintiff and North Carolina Subclass members acted as reasonable consumers would have acted under the circumstances, and entered into the transactions (purchasing the Recalled Devices) that resulted in the damages.

492. Accordingly, pursuant to the aforementioned statutes, Plaintiff and North Carolina Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips’ conduct, Plaintiff and North Carolina Subclass members are entitled to recover statutory, exemplary, treble, and/or punitive damages, together with interest, cost of suit, and

attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

COUNT XXXV
VIOLATIONS OF THE OHIO CONSUMER SALES PRACTICES ACT
Ohio Rev. Code §§ 1345.01, *et seq.* ("CSPA")
On Behalf of the Ohio Subclass

493. Plaintiffs Flick, Fultz, Giordano, Hock, and Stefanini reallege and incorporate by reference all preceding allegations as though fully set forth herein.

494. Plaintiffs Flick, Fultz, Giordano, Hock, and Stefanini bring this action individually and on behalf of the members of the Ohio Subclass.

495. The Ohio Consumer Sales Practices Act was created to protect Ohio consumers from unfair or deceptive business practices.

496. Philips has intentionally engaged in deceptive and unfair acts or practices, false promises and misleading and unconscionable commercial practices, including misleading omissions of material fact, in connection with the advertisement, marketing, promotion and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

497. Plaintiffs and Ohio Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Ohio Rev. Code §§1345.02(A); 1345.03(A). Plaintiffs and Ohio Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

498. Accordingly, pursuant to the aforementioned statutes, Plaintiffs and Ohio Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable

degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, Plaintiffs and Ohio Subclass members are entitled to cost of suit and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

COUNT XXXVI
VIOLATIONS OF THE OKLAHOMA CONSUMER PROTECTION ACT
15 Okla. Stat. Ann. §§ 751, et seq. ("OCPA")
On Behalf of the Oklahoma Subclass

499. Plaintiff Mcelyea realleges and incorporates by reference all preceding allegations as though fully set forth herein.

500. Plaintiff Mcelyea brings this action individually and on behalf of the members of the Oklahoma Subclass.

501. The Oklahoma Consumer Protection Act ("OCPA") was created to protect Oklahoma consumers from unfair methods of competition and unfair or deceptive business practices.

502. Philips has knowingly engaged in deceptive, unconscionable, unlawful, unfair, immoral, unethical, oppressive, unscrupulous, fraudulent and misleading commercial practices, including misleading omissions of material fact, in connection with the marketing, promotion and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

503. Plaintiff and Oklahoma Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use

or employment of a method, act or practice declared unlawful by 15 Okla. Stat. Ann. §§ 752 (13), 752 (14). Plaintiff and Oklahoma Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

504. Accordingly, pursuant to the aforementioned statutes, Plaintiff and Oklahoma Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Oklahoma Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

COUNT XXXVII
VIOLATIONS OF THE OREGON UNLAWFUL TRADE PRACTICES ACT
Or. Rev. Stat. §§646.605, *et seq.* ("UTPA")
On Behalf of the Oregon Subclass

505. Plaintiffs Julie Barrett and Peter Barrett reallege and incorporate by reference all preceding allegations as though fully set forth herein.

506. Plaintiffs Julie Barrett and Peter Barrett bring this action individually and on behalf of the members of the Oregon Subclass.

507. The Oregon Unlawful Trade Practices Act ("UTPA") was created to protect Oregon consumers from fraudulent business practices.

508. Philips has willfully, knowingly, and recklessly engaged in deceptive, unfair, false, fraudulent and misleading commercial practices, including misleading representation, or omissions of material fact, in connection with the marketing, promotion and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

509. Plaintiffs and Oregon Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Or. Rev. Stat. §646.607. Plaintiffs and Oregon Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

510. Accordingly, pursuant to the aforementioned statutes, Plaintiffs and Oregon Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and Oregon Subclass members are entitled to recover statutory, exemplary, treble, and/or punitive damages, together with interest, cost of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

COUNT XXXVIII
VIOLATIONS OF THE PENNSYLVANIA UNFAIR TRADE PRACTICES AND
CONSUMER PROTECTION LAW
73 Pa. Stat. Ann. §§201-1, *et seq.* (“UTPCPL”)
On Behalf of the Pennsylvania Subclass

511. Plaintiff Masington realleges and incorporates by reference all preceding allegations as though fully set forth herein.

512. Plaintiff Masington brings this action individually and on behalf of the members of the Pennsylvania Subclass.

513. The Pennsylvania Unfair Trade Practices and Consumer Protection Law (“UTPCPL”) was created to protect Pennsylvania consumers from fraudulent or deceptive business practices.

514. Philips has knowingly engaged in deceptive, unconscionable, unfair, false, fraudulent and misleading commercial practices, including misleading omissions of material fact, in connection with the marketing, promotion and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

515. Plaintiff and Pennsylvania Subclass members justifiably relied on Philips unlawful conduct in purchasing the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the act or practice declared unlawful by 73 Pa. Stat. Ann. §§201-1, *et seq.* Plaintiff and Pennsylvania Subclass members acted as reasonable consumers would have acted under the circumstances and would not have purchased the Recalled Devices had they known the truth.

516. Accordingly, pursuant to the aforementioned statutes, Plaintiff and Pennsylvania Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages

are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Pennsylvania Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

COUNT XXXIX
VIOLATIONS OF THE SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT
S.C. Code Ann. §§ 39-5-10, *et seq.* ("SCUTPA")
On Behalf of the South Carolina Subclass

517. Plaintiffs William Anderson and Diaz reallege and incorporate by reference all preceding allegations as though fully set forth herein.

518. Plaintiffs William Anderson and Diaz bring this action individually and on behalf of the members of the South Carolina Subclass.

519. The South Carolina Unfair Trade Practices Act ("SCUTPA") was created to protect South Carolina consumers from unlawful business practices.

520. Philips has knowingly engaged in unlawful, unfair, deceptive, immoral, unethical, oppressive, fraudulent and misleading commercial practices, including misleading omissions of material fact, in connection with the marketing, promotion and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

521. Plaintiffs and South Carolina Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by S.C. Code Ann. §§ 39-5-10,

et seq. Plaintiffs and the South Carolina Subclass acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

522. Accordingly, pursuant to the aforementioned statutes, Plaintiffs and South Carolina Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and South Carolina Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

COUNT XL
Texas Deceptive Trade Practices and Consumer Protection Act
Tex. Bus. Comm. Code Ann. §§ 17.41, *et seq.*
On Behalf of the Texas Subclass

523. Plaintiffs Deleon, Lowney, Panzera, and Polk reallege and incorporate by reference all preceding allegations as though fully set forth herein.

524. Plaintiffs Deleon, Lowney, Panzera, and Polk bring this cause of action individually and on behalf of the members of the Texas Subclass.

525. The Texas Deceptive Trade Practices Act ("TDTPA") was created to protect Texas consumers from deceptive and unfair business practices.

526. Philips' conduct described herein constitutes a violation of several of the provisions enumerated in Tex. Bus. & Com. Code Ann. § 17.46(b), including but not limited to, misleading,

misrepresenting, omitting, or supplying false information to consumers as to the source, affiliation, certification, characteristics, ingredients, uses, benefits, quantities, standard, or condition of the Recalled Devices.

527. Plaintiffs and Texas Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Tex. Bus. & Com. Code Ann. § 17.46(b). Plaintiffs and Texas Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

528. Accordingly, pursuant to Tex. Bus. & Com. Code Ann. § 17.50(b)(1), (h), Plaintiffs and Texas Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and Texas Subclass members are entitled to recover treble damages for the willful and knowing violation of the TDTPA and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

529. To the extent that any pre-suit notice was purportedly required, Philips has had notice of its violations for nearly a year. Further, at a minimum on October 28, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter

complying with any required pre-suit notification requirements. Philips has failed to remedy its unlawful conduct.

COUNT XLI
Wisconsin Deceptive Trade Practice Act
Wis. Stat. § 100.18, *et seq.*
On Behalf of the Wisconsin Subclass

530. Plaintiff Matters realleges and incorporates by reference all preceding allegations as though fully set forth herein.

531. Plaintiff Matters brings this cause of action individually and on behalf of the members of the Wisconsin Subclass.

532. The Wisconsin Deceptive Trade Practice Act (“WDTPA”) was created to protect Wisconsin consumers from deceptive and unfair business practices.

533. Philips’ conduct described herein with respect to the Recalled Devices constitutes unfair or deceptive acts or practices and untrue, deceptive or misleading representations made in connection with a sale, making it unlawful under Wis. Stat. § 100.18(1).

534. Plaintiff and Wisconsin Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Wis. Stat. §§ 100.18(2), 100.18(9)(a). Plaintiff and Wisconsin Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips’ unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

535. Accordingly, pursuant to Wis. Stat. § 100.18(11)(b)(2), Plaintiff and Wisconsin Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid

and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Wisconsin Subclass members are entitled to recover attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request, individually and on behalf of the Class and State Subclasses, that this Court:

- A. determine that the claims alleged herein may be maintained as a class action under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the Nationwide Class and Subclasses defined above, and designate Plaintiffs as the class and subclass representatives as specified above and Plaintiffs' counsel as counsel for the Nationwide Class and State Subclasses;
- B. award equitable relief, including but not limited to, requiring Philips to provide restitution and disgorgement of profits;
- C. award all damages to which Plaintiffs and Class members are entitled;
- D. award pre-judgment and post-judgment interest on such monetary relief;
- E. award reasonable attorneys' fees and costs; and
- F. grant such further and other relief that this Court deems appropriate.

JURY DEMAND

Plaintiffs and the Class and Subclasses demand a trial by jury on all issues so triable.

Dated: June 17, 2022

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